Exhibit 10

This document: 1995 CanLII 55 (S.C.C.)
Citation: *Hollis v. Dow Corning Corp.*, [1995] 4 S.C.R. 634, 1995 CanLII 55 (S.C.C.)
Parallel citations: (1995), 129 D.L.R. (4th) 609; (1995), [1996] 2 W.W.R. 77; (1995), 26 B.L.R. (2d) 169; (1995), 14 B.C.L.R. (3d) 1
Date: *1995-12-21*
Docket: *23776*

Hollis *v.* Dow Corning Corp., [1995] 4 S.C.R. 634

Dow Corning Corporation *Appellant*

v.

Susan Hollis and John Robert Birch *Respondents*

Indexed as: Hollis *v.* Dow Corning Corp.

File No.: 23776.

1995: February 2; 1995: December 21.

Present: La Forest, L'Heureux-Dubé, Sopinka, Gonthier, Cory, McLachlin and Iacobucci JJ.

on appeal from the court of appeal for british columbia

Torts -- Manufacturers' duty to warn -- Learned intermediary -- Breast implant ruptured -- Patient not previously warned by doctor of post-surgical risks or of possibility of implant rupture -- Whether or not manufacturer had duty to warn patient and/or doctor -- Whether or not principles of learned intermediary affecting duty of manufacturer to warn patient directly.

Torts -- Causation -- Whether subjective or objective test to patient's decision to undergo surgery knowing risks -- Whether manufacturer entitled to escape liability on what doctor would have done if properly warned.

Practice -- Appellate court powers -- Finding of fact -- Whether finding of fact can be made by appeal court or whether matter should be referred to trial court.

In 1983, Ms. Hollis, on the advice of her surgeon (Dr. Birch), underwent breast implant surgery to correct a congenital deformity. She was not warned by him of the risks of post-surgical complications or of the possibility that the implants might rupture inside her body. In 1984, after further surgery and an examination by Dr. Birch, who gave the opinion that there was no problem with her breasts, Ms. Hollis

began a baker's course which required vigorous upper body movement. In 1985, Ms. Hollis noticed a lump in her right breast and began to feel pain there as well as in her right side. She attended another surgeon, Dr. Quayle, who operated to remove the implant. He discovered that the left implant was intact but that the right implant had ruptured. Dr. Quayle removed the gel from the right implant but could not find the envelope. After the removal of the breast implants, Ms. Hollis' physical condition worsened. A visit to a third surgeon in 1987 resulted in Ms. Hollis' undergoing a successful subcutaneous mastectomy on both breasts and opting for a new, different model of breast implants.

Dr. Birch received little warning from the implant manufacturer as to the possibility of the implants' rupturing. Even as early as 1979, Dow was aware that implant ruptures could cause adverse reactions in the body arising from loose gel. While the 1985 warning referred to the dangers of "enlarged lymph nodes, scar formation, inflammation" and the potential, after a rupture, for "distant migration of the gel", the 1976 and 1979 warnings made no reference to any such potential consequences. Nor did these earlier warnings make reference to rupture occurring from anything less than "abnormal squeezing or trauma".

Ms. Hollis brought action in 1989 against Dow, Dow's Canadian agent, Dr. Birch and Dr. Quayle. At trial, she successfully claimed against Dow for the negligent manufacture of the breast implant and was awarded damages and costs; her other claims were dismissed. A majority of the Court of Appeal overturned the finding that Dow had negligently manufactured the implant, but dismissed the appeal on the ground that Dow had failed to warn Ms. Hollis adequately concerning the risks of rupture. A majority of the Court of Appeal allowed Ms. Hollis' appeal from the dismissal of her action against Dr. Birch and ordered a new trial in respect of that claim. The sole issue here is whether the Court of Appeal erred in finding Dow liable to the Ms. Hollis for failing to warn Dr. Birch adequately of the risk of a post-surgical implant rupture.

Held (Sopinka and McLachlin JJ. dissenting): The appeal should be dismissed.

Per La Forest, L'Heureux-Dubé, Gonthier, Cory and Iacobucci JJ.: A manufacturer of a product has a duty in tort to warn consumers of dangers it knows or ought to know are inherent in the product's use. This duty is a continuing one, requiring manufacturers to warn not only of dangers known at the time of sale, but also of dangers discovered after the product has been sold and delivered. All warnings must be reasonably communicated, and must clearly describe any specific dangers that arise from the ordinary use of the product. The duty to warn serves to correct the knowledge imbalance between manufacturers and consumers by alerting consumers to any dangers and allowing them to make informed decisions concerning the safe use of the product. The nature and scope of this duty varies with the level of danger entailed by the ordinary use of the product. In the case of medical products, the standard of care to be met by manufacturers in ensuring that consumers are properly warned is necessarily high.

The principles underlying the doctrine of "informed consent" apply to the relationship between manufacturers of medical products and consumers. The manufacturer-consumer relationship, unlike the doctor-patient relationship, is characterized primarily by a lack of direct communication which creates a relationship of complete dependency between manufacturer and patient. Manufacturers, therefore, can be reasonably required to make clear, complete and current informational disclosure to consumers concerning the risks inherent in the ordinary use of their products. A high standard for disclosure protects public health and yet does not place an onerous burden on manufacturers.

The "learned intermediary" rule applies where an intermediate inspection of the product is anticipated because the product is highly technical in nature or where a consumer is placing primary reliance on the judgment of a "learned intermediary" and not the manufacturer. In such cases, a warning to the ultimate consumer may not be necessary and the manufacturer may satisfy its duty to warn the ultimate

consumer by warning the learned intermediary of the risks inherent in the use of the product. This rule generally applies either where a product is highly technical in nature and is intended to be used only under the supervision of experts, or where the nature of the product is such that the consumer will not realistically receive a direct warning from the manufacturer before using the product. The rule, which is in essence an application of the common law principle of intermediate examination and intervening cause, is an exception to the general manufacturer's duty to warn the consumer and operates to discharge the manufacturer's duty to the ultimate consumer, who has a right to full and current information about any risks inherent in the ordinary use of the product. The rule presumes that the intermediary is "learned", i.e., fully apprised of the risks associated with the use of the product. Accordingly, the manufacturer can only be said to have discharged its duty to the consumer when the intermediary's knowledge approximates that of the manufacturer. To allow manufacturers to claim the benefit of the rule where they have not fully warned the physician would undermine the policy rationale for the duty to warn, which is to ensure that the consumer is fully informed of all risks. Since the manufacturer is in the best position to know the risks attendant upon the use of its product and is also in the best position to ensure that the product is safe for normal use, the primary duty to give a clear, complete, and current warning must fall on its shoulders.

The "learned intermediary" rule is applicable in the context of this case. Dow's warning to the surgeon here was inadequate, however. There was sufficient evidence on the record to allow the Court of Appeal to make a full and proper re-assessment of the duty to warn issue without sending the case back to trial. While appellate courts are generally, and justifiably, wary of making findings of fact without having the advantage of seeing and hearing testimony first-hand, such concerns do not arise here because the bulk of the critical evidence adduced at trial was documentary, not testimonial.

The earlier warnings given the medical profession by the manufacturer implied that rupture would occur only in extreme cases of violent impact. The 1985 warning, however, made it clear that a patient who received an implant would have to consider altering her lifestyle to avoid rupture. A more accurate warning could quite reasonably have affected Ms. Hollis' choice of professional and her resulting exposure to unnecessary risk.

Dow knew or should have known of the risks referred to in the 1985 warning when the surgery was performed in 1983. Between 1976 and 1984, Dow received 78 field reports from doctors of post-operative "unexplained" ruptures occurring in its implants. It had a duty to convey its findings concerning both the "unexplained" rupture phenomenon and the possible harm caused by loose gel inside the body to the medical community much sooner than it did. Since implants are surgically placed inside the human body, and given that any defects in these products will obviously have a highly injurious effect on the user, the onus on Dow to be forthcoming with information was extremely high throughout the relevant period. The duty to warn is a continuing one and manufacturers of potentially hazardous products have an obligation to keep doctors abreast of developments even if they do not consider those developments to be conclusive.

Arguments based upon the assumption that Dow only had the obligation to warn once it had reached its own definitive conclusions with respect to the cause and effect of the "unexplained" ruptures necessarily failed. This assumption has no support in the law of Canada. Although the number of ruptures was statistically small over the relevant period and the cause of the ruptures was unknown, Dow had an obligation to take into account the seriousness of the risk posed by a potential rupture to each user of its implant. Indeed, it is precisely because the ruptures were "unexplained" that Dow should have been concerned. Certainly, it would not have been onerous for Dow to have included an update in their product inserts to the effect that "unexplained" ruptures had been reported which were not attributable to surgical procedures, and a list of the possible side-effects of such ruptures.

With respect to causation, the subjective test (established in *Buchan*) as to whether or not the

patient would have undergone the surgery if fully informed was adopted. The most serious concern raised about its application is that the plaintiff, with the benefit of hindsight, will always claim that she would not have used the product if she had been properly warned. In a suit against a manufacturer for failure to warn, this concern can be adequately addressed at the trial level through cross-examination and through a proper weighing by the trial judge of the relevant testimony. A manufacturer of products cannot be considered coterminous with a physician whose duty is to give the best medical advice and service possible to a patient in a specific context. A manufacturer, given the greater likelihood to overvalue a product and underemphasize its risk, should from a policy perspective be held to a strict standard of warning consumers of dangerous side effects to these products. There is no reason, as in the case of a doctor, to modify the usual approach to causation followed in other tortious actions. Indeed the imbalance of resources and information between the manufacturer and the patient, and even the doctor, weighs in the opposite direction. Sufficient evidence was adduced here to satisfy the subjective test.

While some ambiguity existed as to Dr. Birch's warning practices in 1983, Dow cannot argue on this basis that no direct causal link existed between its breach of duty and the injuries suffered by the plaintiff. It is true that had Dr. Birch been adequately warned and not passed on the information to Ms. Hollis, Dow would have been absolved of liability by virtue of the learned intermediary doctrine. It does not follow from this, however, that, for Dow to be liable, Ms. Hollis must now establish that Dr. Birch would have informed her if he had known. To require her to do so would be to ask her to prove a hypothetical situation relating to her doctor's conduct -- a situation only brought about by Dow's failure to perform its duty. While the legal and persuasive onus in a negligence case generally falls on the plaintiff, the plaintiff is not required to prove a hypothetical situation of this kind.

The victim's power of proof is seriously undermined if called upon to prove what a doctor would have done in a hypothetical situation. The governing principle in a case of this nature is informed consent, namely, the right of the patient to be fully informed by the manufacturer of all material risks associated with the use of a medical product. This right to informed consent was not respected in this case. Dow's failure to warn was a cause of her injury; whether Dr. Birch's actions in the hypothetical situation posited by Dow might also have been a cause is not a matter for Ms. Hollis to prove. Ms. Hollis, who was in a position of great informational inequality with respect to both the manufacturer and the doctor, played no part in creating the set of causal conditions leading to her injury. Justice dictates that she should not be penalized for the fact that had the manufacturer actually met its duty to warn, the doctor still might have been at fault.

A manufacturer should not be able to escape liability for failing to give a warning it was under a duty to give by simply presenting evidence tending to establish that even if the doctor had been given the warning, he or she would not have passed it on to the patient, let alone putting an onus on the plaintiff to do so. Adopting such a rule would, in some cases, run the risk of leaving the plaintiff with no compensation for her injuries. She would not be able to recover against a doctor who had not been negligent with respect to the information that he or she did have; yet she also would not be able to recover against a manufacturer who, despite having failed in its duty to warn, could escape liability on the basis that, had the doctor been appropriately warned, he or she still would not have passed the information on to the plaintiff. Our tort law should not be held to contemplate such an anomalous result.

Per Sopinka and McLachlin JJ. (dissenting): La Forest J.'s analysis of the principles relating to the duty to warn, and in particular the way the learned intermediary principles apply, were agreed with.

The subjective test put forward in *Buchan v. Ortho Pharmaceutical (Canada) Ltd.* places no reliance on evidence as to what a reasonable woman would do and also fails to take into account the inherent unreliability of the plaintiff's self-serving assertion. The most reliable approach in determining what would in fact have occurred is to test the plaintiff's assertion by reference to objective evidence as to what a reasonable person would have done. This difficult question of fact, notwithstanding the test

adopted, should be determined at trial and not on appeal. The test for determining the same issue should not be different for the physician and the manufacturer.

To establish liability, the plaintiff must show not only a breach of duty by the defendant, but also that the breach in question was the cause of the plaintiff's injury. Here, Ms. Hollis must show that her doctor would have warned her of any dangers that had been brought to his attention and that if warned she would have refused the operation. Absent this form of proof, it cannot be said with any degree of certainty that the failure of Dow to warn physicians was the cause of the injuries suffered. The absence of cause cannot be finessed by sweeping it under the apportionment rug.

The cases referred to by La Forest J. with respect to reversal or relaxation of the burden of proof with respect to causation do not support treating causation as irrelevant. In any event the cases referred to do not support reversing the burden of proof in this case or, if they did, the issue of causation would not be resolved. There was abundant evidence to raise the issue of causation which should be weighed by the trial judge at a new trial.

A new trial should be ordered when disposing of an appeal on a legal basis that was not dealt with or resolved at trial and where crucial findings of fact concerning that issue were not made by the trial judge. A court of appeal is extremely reluctant to assume the role of the trial judge in making factual findings essential to resolving an issue. More importantly, there is considerable support for the view that the party affected is entitled to a new trial virtually as of right.

An appellate court may be in as good a position as a trial judge to make a factual finding in the following limited circumstances: (i) the trial judge has made the necessary findings albeit in respect of a different legal issue, or it can be safely assumed from findings actually made that but for the error of law the necessary findings would have been made; (ii) the evidence is not in dispute or conflict and no issue of credibility is involved; (iii) special circumstances exist in which the parties urge the appellate court to make necessary findings of fact. No circumstances were present which would bring this case within these criteria and this Court was clearly not in as good a position as the trial judge to make the requisite findings.

In addition to addressing issues relating to the duty, factual issues needed to be decided. No findings were made at trial as to whether Ms. Hollis would have consented to the operation, even if properly warned and as to whether Dr. Birch's conduct would have been the same whether or not Dow was in breach of the duty to warn. In the absence of a finding in this Court that evidence was lacking to raise the issues or that a weighing of the evidence cannot resolve the matter, a new trial would enable the trial judge to carry out this function. In any event, a new trial will be held with respect to Dr. Birch, and the judgment of this Court will not put an end to the litigation. This Court should not decide the issue because a subsequent trial judge would then not be able to decide otherwise. Finally, under the *Negligence Act*, where damage or loss is caused by the fault of two or more persons, liability for the damage should be apportioned in accordance with the degrees of fault.

Cases Cited

By La Forest J.

Approved: *Buchan v. Ortho Pharmaceutical (Canada) Ltd.* 1986 CanLII 114 (ON C.A.), (1986), 12 O.A.C. 361; **considered:** *Cook v. Lewis*, 1951 CanLII 1 (S.C.C.), [1951] S.C.R. 830; **referred to:** *Lambert v. Lastoplex Chemicals Co.*, [1972] S.C.R. 569; *Rivtow Marine Ltd. v. Washington Iron Works*, [1974] S.C.R. 1189; *Setrakov Construction Ltd. v. Winder's Storage & Distributors Ltd.* (1981), 11 Sask. R. 286; *Meilleur v. U.N.I.-Crete Canada Ltd.* (1985), 32 C.C.L.T. 126; *Skelhorn v. Remington Arms Co.* reflex, (1989), 69 Alta. L.R. (2d) 298; *McCain Foods Ltd. v. Grand Falls Industries Ltd.* reflex,

(1991), 116 N.B.R. (2d) 22; *Donoghue v. Stevenson*, [1932] A.C. 562; *Shandloff v. City Dairy*, [1936] 4 D.L.R. 712; *Arendale v. Canada Bread Co.*, [1941] 2 D.L.R. 41; *Zeppa v. Coca-Cola Ltd.*, [1955] 5 D.L.R. 187; *Rae and Rae v. T. Eaton Co. (Maritimes) Ltd.* (1961), 28 D.L.R. (2d) 522; *Heimler v. Calvert Caterers Ltd.* (1975), 8 O.R. (2d) 1; *Hopp v. Lepp*, 1980 CanLII 14 (S.C.C.), [1980] 2 S.C.R. 192; *Reibl v. Hughes*, 1980 CanLII 23 (S.C.C.), [1980] 2 S.C.R. 880; *Ciarlariello v. Schacter*, 1993 CanLII 138 (S.C.C.), [1993] 2 S.C.R. 119; *Schloendorff v. Society of New York Hospital*, 105 N.E. 92 (1914); *Canterbury v. Spence*, 464 F.2d 772 (1972); *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82 (1966); *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (1974), *cert.* denied 419 U.S. 1096 (1974); *Schenebeck v. Sterling Drug, Inc.*, 423 F.2d 919 (1970); *Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132 (1973); *Dunkin v. Syntex Laboratories, Inc.*, 443 F.Supp. 121 (1977); *Lindsay v. Ortho Pharmaceutical Corp.*, 637 F.2d 87 (1980); *Timm v. Upjohn Co.*, 624 F.2d 536 (1980), *cert.* denied 449 U.S. 1112 (1981); *Stanback v. Parke, Davis and Co.*, 657 F.2d 642 (1981); *Walker v. Merck & Co.*, 648 F.Supp. 931 (1986), aff'd 831 F.2d 1069 (1987); *Plummer v. Lederle Laboratories*, 819 F.2d 349 (1987); *Davidson v. Connaught Laboratories* (1980), 14 C.C.L.T. 251; *Holmes v. Ashford*, [1950] 2 All E.R. 76; *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65 (1985), *cert.* denied 474 U.S. 250 (1985); *Prudential Trust Co. v. Forseth*, [1960] S.C.R. 210; *Davie Shipbuilding Ltd. v. The Queen*, [1984] 1 F.C. 461; *Nova, An Alberta Corporation v. Guelph Engineering Co.* reflex, (1989), 70 Alta. L.R. (2d) 97; *McCue v. Norwich Pharmacal Co.*, 453 F.2d 1033 (1972); *Hamilton v. Hardy*, 549 P.2d 1099 (1976).

By Sopinka J. (dissenting)

Buchan v. Ortho Pharmaceutical (Canada) Ltd. 1986 CanLII 114 (ON C.A.), (1986), 12 O.A.C. 361; *Cobbs v. Grant*, 502 P.2d 1 (1972); *Reibl v. Hughes*, 1980 CanLII 23 (S.C.C.), [1980] 2 S.C.R. 880; *Cook v. Lewis*, 1951 CanLII 1 (S.C.C.), [1951] S.C.R. 830; *Snell v. Farrell*, 1990 CanLII 70 (S.C.C.), [1990] 2 S.C.R. 311; *McGhee v. National Coal Board*, [1973] 1 S.L.T.R. 14; *Wilsher v. Essex Area Health Authority*, [1988] A.C. 1074; *Just v. British Columbia*, 1989 CanLII 16 (S.C.C.), [1989] 2 S.C.R. 1228; *Koschman v. Hay* (1977), 17 O.R. (2d) 557; *Chan v. Canada (Minister of Employment and Immigration)*, 1995 CanLII 71 (S.C.C.), [1995] 3 S.C.R. 593; *Davie Shipbuilding Ltd. v. The Queen*, [1984] 1 F.C. 461; *Jardine v. Northern Co-operative Timber and Mill Association*, [1945] 1 W.W.R. 533; *Nova, An Alberta Corporation v. Guelph Engineering Co.* reflex, (1989), 70 Alta. L.R. (2d) 97; *Glow v. Paquin*, [1932] 1 W.W.R. 737; *Patterson v. Township of Aldborough* (1913), 11 D.L.R. 437; *Colautti Construction Ltd. v. City of Ottawa* (1984), 9 D.L.R. (4th) 265; *Bank of Nova Scotia v. Dunphy Leasing Enterprises Ltd.* 1991 CanLII 2721 (AB C.A.), (1991), 83 Alta. L.R. (2d) 289; *Fitz Randolph v. Fitz Randolph* (1918), 41 D.L.R. 739; *McCarroll v. Powell*, [1955] 4 D.L.R. 631; *Hunt v. MacLeod Construction Co.*, [1958] S.C.R. 737.

Statutes and Regulations Cited

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Sale of Goods Act, R.S.B.C. 1979, c. 370.

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Peppin, Patricia. "Drug/Vaccine Risks: Patient Decision-Making and Harm Reduction in the Pharmaceutical Company Duty to Warn Action" (1991), 70 *Can. Bar Rev.* 473.

APPEAL from a judgment of the British Columbia Court of Appeal 1993 CanLII 949 (BC C.A.), (1993), 81 B.C.L.R. (2d) 1, 103 D.L.R. (4th) 520, 48 W.A.C. 108, [1993] 6 W.W.R. 609, 16 C.C.L.T. (2d) 140, ordering a new trial (with respect to John Robert Birch) and dismissing an appeal (with respect to Dow Corning Corporation) from a judgment of Bouck J., [1990] B.C.J. No. 1059, allowing Susan Hollis' action against Dow Corning Corporation and dismissing her action against John Robert Birch. Appeal dismissed, Sopinka and McLachlin JJ. dissenting.

D. J. Mullan, Q.C., and *D. W. Donohoe*, for the appellant.

Donald J. McKinlay, for the respondent Susan Hollis.

James M. Lepp and *William S. Clark*, for the respondent John Robert Birch.

The judgment of La Forest, L'Heureux-Dubé, Gonthier, Cory and Iacobucci JJ. was delivered by

1 LA FOREST J. -- The question raised in this appeal is whether a manufacturer of silicone breast implants may be held liable in tort to a patient who suffers injuries from an unexplained rupture in the implants when the manufacturer has failed to give adequate warning to the patient or the surgeon concerning the risks of rupture. The appellant, Dow Corning Corporation ("Dow"), is a United States corporation which, during the course of the 1970s and 1980s, developed and manufactured the silicone breast implant carrying the trade name "Silastic". On May 7, 1990, Bouck J. of the Supreme Court of British Columbia awarded damages and costs against Dow to the respondent, Susan Hollis, for the negligent manufacture of a Silastic breast implant that ruptured in her body approximately 17 months after it was implanted in 1983. Hollis' claims against the respondent Dr. John Robert Birch, who inserted the implant, Dr. James Quayle, who subsequently removed the implant, and Dow Corning Canada Inc. ("Dow Canada"), the Canadian sales agent for Dow, were dismissed. A majority of the Court of Appeal overturned Bouck J.'s finding that Dow had negligently manufactured the implant, but dismissed the appeal on the ground that Dow had failed to warn Ms. Hollis adequately concerning the risks of rupture. A majority of the Court of Appeal also ordered a new trial with respect to Ms. Hollis' claim against Dr. Birch.

2 Dow was granted leave by this Court to appeal the Court of Appeal's finding that Dow had breached its duty to warn, and asks this Court either to dismiss Ms. Hollis' claim or to order a new trial. For the reasons that follow, it is my view that Dow's appeal should be dismissed. The relevant facts are as follows.

Facts

3 In early June, 1983, Ms. Hollis, then 23 years old, was given a complete physical examination by her family physician, Dr. Ken Mills. Ms. Hollis was a shy and quiet woman who had never before had a complete physical examination. During the course of the examination, Dr. Mills determined that Ms. Hollis suffered from a congenital deformity of the breasts called "tubular breasts", which produced a cylinder-like shape in her breasts and caused blood to collect in the nipple area, resulting in a larger than normal areola. Ms. Hollis told Dr. Mills that she had suspected for several years that her breasts were deformed, and had been self-conscious about them, but that she had never felt the deformity was sufficiently serious to merit medical attention. Despite Ms. Hollis' reservations concerning her need for medical treatment, Dr. Mills suggested that she see

Dr. John Birch, an experienced plastic surgeon, whom Ms. Hollis had seen earlier that year for treatment of a severe case of acne scarring on her cheeks.

4 Ms. Hollis met with Dr. Birch in July, 1983. During the meeting, Dr. Birch informed her that her breasts were indeed deformed and explained that surgery and implants could correct the shape of her breasts and the size of her areolae. Dr. Birch showed Ms. Hollis an implant and explained the surgical implantation procedure. He also told her that she would not be able to feel the implants inside her after the operation and that they would not prevent her from breast-feeding. However, Dr. Birch did not warn Ms. Hollis that there were risks of post-surgical complications. He also failed to warn her of the possibility that the implants might rupture inside her body. On the basis of Dr. Birch's advice, Ms. Hollis consented to surgery.

5 On October 21, 1983, Ms. Hollis underwent surgery for the implantation of two Silastic silicone breast implants at the Kelowna General Hospital in Kelowna, B.C. The implants were "gel-filled, low profile round" Silastic implants manufactured by the appellant Dow and purchased by Dr. Birch from Dow's Canadian agent, Dow Canada. These implants are sold only to doctors or medical establishments and are not directly available to the public. The operation went smoothly and Ms. Hollis experienced a normal recovery. However, by the spring of 1984, the abnormality in Ms. Hollis' breasts had returned. Dr. Birch operated on Ms. Hollis a second time. During the second operation, the plastic surgeon assisting Dr. Birch stretched the areolae of the breasts, which involved the application of light pressure to the breasts. In April, 1984, Ms. Hollis was examined by Dr. Birch, who found no problems with the breasts. On May 15, 1984, Ms. Hollis started a baker's course, which involved heavy upper body and arm movements.

6 In January, 1985, Ms. Hollis noticed a lump in her right breast, and began to feel pain there as well as in her right side. Concerned that the lump might be related to the implant, she went to see Dr. Quayle, another plastic surgeon, who referred her to Dr. Turner, an expert in breast surgery. Dr. Turner concluded that the lump was likely related to the downward slippage of the implants, although he noted that it could represent an area of benign breast disease. Dr. Turner recommended the removal of the implants. On January 29, 1985, Ms. Hollis was again examined by Dr. Quayle. He noted a degree of fullness in the right lower breast. She complained that her right side was becoming very painful.

7 On March 19, 1985, Dr. Quayle operated to remove the implants. He discovered that the left implant was intact but that the right implant had ruptured, causing irritation to the walls of the cavity in the right breast where the gel had come into contact with the tissue. The silicone gel from the right implant was lying in the breast cavity, which was red and swollen. Dr. Quayle removed the gel with sponges but was unable to find the silicone envelope that had surrounded the gel when the implant was originally inserted. Dr. Quayle did not preserve the gel for analysis, but returned the left implant to Ms. Hollis. The cause of the rupture of the implant in the right breast remains unknown.

8 After the removal of the breast implants, Ms. Hollis' physical condition worsened. Between May 1985 and February 1987, she continued to experience pain in her right breast and armpit and once again developed lumps in her right breast. The pain was especially severe when she raised her right arm and when she was busy at work. During that time, she met with several doctors and underwent numerous tests. On February 3, 1987, Dr. A. D. Courtemanche, a plastic surgeon, operated on Ms. Hollis and found a tender elongated mass in both lower quadrants of her right breast, which he thought was probably a remnant of the breast implant, although he did not find any silicone in the right breast. On June 10, 1987, Dr. Courtemanche performed a subcutaneous mastectomy on both breasts. For cosmetic purposes, Ms. Hollis elected to have Dr. Courtemanche

implant two Dow Silastic II implants. These implants were of a different model and make-up than the original Silastic implants.

9 The subcutaneous mastectomy was successful, and Ms. Hollis has suffered no further complications since 1987. However, there is still residual scarring around the breasts and Ms. Hollis maintains a lingering belief that the ruptured envelope remains somewhere inside her body. She is worried that the new implants will break if she does routine exercises or returns to any vigorous job such as baking. These concerns have caused Ms. Hollis to suffer depression, for which she has received psychiatric help.

10 Ms. Hollis brought action in 1989 against Dow, Dow's Canadian agent, Dr. Birch and Dr. Quayle. The claim against Dow was for negligence in the manufacture of the implant placed in her right breast and, alternatively, for failure of a duty to give adequate warning to the medical profession or the public of the possibility that the implants could rupture. The claim against Dow's agent was for failure to warn about the possibility that the implant might rupture. The claims against Dr. Birch were for negligent advice and negligent surgery with respect to the original implants, as well as a claim, under the *Sale of Goods Act*, R.S.B.C. 1979, c. 370, that he sold her the implants when they were not fit for their intended purpose. The claims against Dr. Quayle were for negligence in failing to operate and remove the implants promptly when he discovered there might be a defect, and for failing to remove all the remnants of the gel from her right breast.

Judgments of the Courts Below

British Columbia Supreme Court, [1990] B.C.J. No. 1059 (Bouck J.)

11 Bouck J. found Dow liable to Ms. Hollis for negligently manufacturing the Silastic implants. He proceeded on the basis that there were four possible causes of the rupture: (i) an act or omission by Dr. Birch in inserting the implant; (ii) an act or omission by Dr. Quayle in removing the implant; (iii) external trauma to the implant during the time it was in Ms. Hollis' body; and (iv) an inadequacy in the design or manufacture of the implant. He made findings of fact that eliminated all causes of rupture except faulty manufacturing and, on that basis, reasoned that Dow was negligent either by inference or through the application of the doctrine of *res ipsa loquitur*. He stated:

> I already found Dr. Birch took proper care to ensure the prosthesis remained undamaged from the time he took possession of it until he finished the surgical implantation. There is no evidence Dr. Quayle punctured the envelope when he removed it from the right breast of Miss Hollis. All the evidence is to the effect the implant ruptured at some earlier time. Nor is there anything to indicate Miss Hollis intentionally or unintentionally abused the implant in any way. She made use of it in the normal manner contemplated by Dow Corporation. All of these findings rebut the defendants' suggestion that the implant was damaged by others who had control of it, thus allowing the application of the doctrine of *res ipsa loquitur*.

Bouck J. drew further support for his conclusion from the fact that Dow had "replaced" the Silastic implant during the mid-1980s with the thicker and more durable Silastic II model. He observed that Dow had introduced the Silastic II "to counteract that defect in the earlier Silastic implant" and in response to 78 field reports Dow had received between 1975 and 1984 of unexplained ruptures in the Silastic implants. This, he reasoned, "is a piece of evidence from which an inference of negligence can be drawn".

12 Having found Dow liable for negligent manufacture, Bouck J. did not proceed to address Ms. Hollis' subsidiary claim that Dow had breached its duty to warn Ms. Hollis or the medical

profession of the possibility of post-surgical implant rupture.

13 Bouck J. dismissed the actions against Dow Canada, Dr. Birch and Dr. Quayle. With respect to the claim against Dr. Birch, he found that Dr. Birch had not fallen below the standard of care for doctors in 1983, when he performed the surgery on Ms. Hollis, because the possibility of rupture of gel-filled implants was neither well-known to the medical community in 1983 nor prevalent in the medical literature. With respect to the claim against Dr. Quayle, Bouck J. found no evidence of negligence, and concluded that Dr. Quayle had followed the correct medical procedures throughout. With respect to the claim against Dow Canada, he found that Dow Canada did not breach its duty to warn consumers or doctors about the risk of rupture because it was only a sales agent; he further found that it did not contribute any technical knowledge to the production of the product, and therefore had insufficient knowledge in 1983 that the implants were defectively manufactured.

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14 A majority of the Court of Appeal dismissed Dow's appeal from Bouck J.'s finding of liability by Dow, but allowed Ms. Hollis' appeal from Bouck J.'s dismissal of the action against Dr. Birch, ordering a new trial solely to resolve the question of Dr. Birch's liability to Ms. Hollis.

15 With respect to Dow's appeal, the Court of Appeal was unanimous in ruling that Bouck J. had erred in drawing an inference of negligence against Dow, finding that he had based his decision upon two erroneous factual findings: first, that the Silastic II implant "replaced" the Silastic I during the 1980s, when these two products in fact shared the market from mid-1983 until late 1987 and, second, that the evidence adduced at trial eliminated Ms. Hollis as a possible cause of the rupture. However, Prowse J.A., writing for a majority of the Court of Appeal on this issue (McEachern C.J.B.C. concurring), dismissed the appeal on the ground that Dow had failed to provide either Ms. Hollis or Dr. Birch with adequate warnings of the risk of post-surgical implant rupture arising from ordinary, non-traumatic, human activities.

16 Although Bouck J. declined to rule on the duty to warn issue, Prowse J.A. found there was sufficient evidence adduced at trial to substantiate Ms. Hollis' claim. In particular, Prowse J.A. found it significant that Dow had received reports of between 77 and 81 "unexplained" post-surgical implant ruptures during the period from 1975 to 1984, the majority of which were received prior to 1984, yet failed to warn the medical community until 1985 that the life expectancy of any implant was unpredictable and that an implant could rupture for a variety of reasons, including normal use. Prowse J.A. also ruled that Dow's breach of its duty to warn was the cause of Ms. Hollis' injuries, finding that a reasonable woman in Ms. Hollis' position would not have consented to the surgery in the face of an adequate warning. In support of this conclusion, Prowse J.A. observed that the surgery on Ms. Hollis was not medically necessary and that, in contrast to many women who consent to breast implant surgery, Ms. Hollis was not "pre-sold" when she first went to see Dr. Birch.

17 Southin J.A. dissented with respect to the duty to warn, observing, at p. 34, that Bouck J.'s failure to rule on this issue had created an "absence of findings on crucial issues of fact". Southin J.A. also ruled (McEachern C.J.B.C. concurring) that a new trial was necessary to resolve the question of Dr. Birch's liability. Southin J.A. decided that Bouck J. had erred in concluding that Dr. Birch did not have knowledge of the risk of rupture in 1983, but concluded that a new trial was necessary to determine whether that risk was material and whether its non-disclosure caused Ms. Hollis' injury. Prowse J.A. dissented on this issue, deciding that Dr. Birch had knowledge of the

risk in 1983 and, as a result, found him liable for negligently failing to warn Ms. Hollis of the risk of implant rupture.

Analysis

18 The sole issue raised in this appeal is whether the Court of Appeal erred in finding Dow liable to the respondent Ms. Hollis for failing adequately to warn the implanting surgeon, Dr. Birch, of the risk of a post-surgical implant rupture inside Ms. Hollis' body. The appellant Dow does not contest Bouck J.'s factual finding that Ms. Hollis' seven-year surgical ordeal caused her great physical and psychological pain, residual scarring on her breasts, and a loss of past and future income. However, Dow submits that it was not responsible for Ms. Hollis' injuries. In support of this submission, Dow argues, first, that the warning it gave Dr. Birch was adequate and sufficient to satisfy its duty to Ms. Hollis, and second, that even if it did breach its duty to warn Ms. Hollis, this breach was not the proximate cause of her injuries.

19 For the reasons that follow, it is my view that the Court of Appeal reached the correct conclusion and that the appeal should be dismissed. Since Dow does not challenge the trial judge's findings concerning Ms. Hollis' injuries, I will concentrate on the issues of duty and causation which form the basis for Dow's submissions in this appeal. In the first part of these reasons, I will address the question whether Dow breached its duty to warn, and the related question whether Dow can rely on the so-called "learned intermediary" rule to absolve itself of liability. In the second part, I will consider whether Dow's failure to warn was a proximate cause of Ms. Hollis' injuries.

1. *Dow's Duty to Warn and the "Learned Intermediary" Rule*

(a) The General Principles

(i) *The Duty to Warn*

20 It is well established in Canadian law that a manufacturer of a product has a duty in tort to warn consumers of dangers inherent in the use of its product of which it has knowledge or ought to have knowledge. This principle was enunciated by Laskin J. (as he then was), for the Court, in *Lambert v. Lastoplex Chemicals Co.*, [1972] S.C.R. 569, at p. 574, where he stated:

> Manufacturers owe a duty to consumers of their products to see that there are no defects in manufacture which are likely to give rise to injury in the ordinary course of use. Their duty does not, however, end if the product, although suitable for the purpose for which it is manufactured and marketed, is at the same time dangerous to use; and if they are aware of its dangerous character they cannot, without more, pass the risk of injury to the consumer.

The duty to warn is a continuing duty, requiring manufacturers to warn not only of dangers known at the time of sale, but also of dangers discovered after the product has been sold and delivered; see *Rivtow Marine Ltd. v. Washington Iron Works*, [1974] S.C.R. 1189, at p. 1200, *per* Ritchie J. All warnings must be reasonably communicated, and must clearly describe any specific dangers that arise from the ordinary use of the product; see, for example, *Setrakov Construction Ltd. v. Winder's Storage & Distributors Ltd.* (1981), 11 Sask. R. 286 (C.A.); *Meilleur v. U.N.I.-Crete Canada Ltd.* (1985), 32 C.C.L.T. 126 (Ont. H.C.); *Skelhorn v. Remington Arms Co.* reflex, (1989), 69 Alta. L.R. (2d) 298 (C.A.); *McCain Foods Ltd. v. Grand Falls Industries Ltd.* reflex, (1991), 116 N.B.R. (2d) 22 (C.A.).

21 The rationale for the manufacturer's duty to warn can be traced to the "neighbour principle", which lies at the heart of the law of negligence, and was set down in its classic form by Lord Atkin

in *Donoghue v. Stevenson*, [1932] A.C. 562 (H.L.). When manufacturers place products into the flow of commerce, they create a relationship of reliance with consumers, who have far less knowledge than the manufacturers concerning the dangers inherent in the use of the products, and are therefore put at risk if the product is not safe. The duty to warn serves to correct the knowledge imbalance between manufacturers and consumers by alerting consumers to any dangers and allowing them to make informed decisions concerning the safe use of the product.

22 The nature and scope of the manufacturer's duty to warn varies with the level of danger entailed by the ordinary use of the product. Where significant dangers are entailed by the ordinary use of the product, it will rarely be sufficient for manufacturers to give general warnings concerning those dangers; the warnings must be sufficiently detailed to give the consumer a full indication of each of the specific dangers arising from the use of the product. This was made clear by Laskin J. in *Lambert*, *supra*, where this Court imposed liability on the manufacturer of a fast-drying lacquer sealer who failed to warn of the danger of using the highly explosive product in the vicinity of a furnace pilot light. The manufacturer in *Lambert* had placed three different labels on its containers warning of the danger of inflammability. The plaintiff, an engineer, had read the warnings before he began to lacquer his basement floor and, in accordance with the warnings, had turned down the thermostat to prevent the furnace from turning on. However, he did not turn off the pilot light, which caused the resulting fire and explosion. Laskin J. found the manufacturer liable for failing to provide an adequate warning, deciding that none of the three warnings was sufficient in that none of them warned specifically against leaving pilot lights on near the working area. At pages 574-75, he stated:

> Where manufactured products are put on the market for ultimate purchase and use by the general public and carry danger (in this case, by reason of high inflammability), although put to the use for which they are intended, the manufacturer, knowing of their hazardous nature, has a duty to specify the attendant dangers, which it must be taken to appreciate in a detail not known to the ordinary consumer or user. A general warning, as for example, that the product is inflammable, will not suffice where the likelihood of fire may be increased according to the surroundings in which it may reasonably be expected that the product will be used. The required explicitness of the warning will, of course, vary with the danger likely to be encountered in the ordinary use of the product.

23 In the case of medical products such as the breast implants at issue in this appeal, the standard of care to be met by manufacturers in ensuring that consumers are properly warned is necessarily high. Medical products are often designed for bodily ingestion or implantation, and the risks created by their improper use are obviously substantial. The courts in this country have long recognized that manufacturers of products that are ingested, consumed or otherwise placed in the body, and thereby have a great capacity to cause injury to consumers, are subject to a correspondingly high standard of care under the law of negligence; see *Shandloff v. City Dairy*, [1936] 4 D.L.R. 712 (Ont. C.A.), at p. 719; *Arendale v. Canada Bread Co.*, [1941] 2 D.L.R. 41 (Ont. C.A.), at pp. 41-42; *Zeppa v. Coca-Cola Ltd.*, [1955] 5 D.L.R. 187 (Ont. C.A.), at pp. 191-93; *Rae and Rae v. T. Eaton Co. (Maritimes) Ltd.* (1961), 28 D.L.R. (2d) 522 (N.S.S.C.), at p. 535; *Heimler v. Calvert Caterers Ltd.* (1975), 8 O.R. (2d) 1 (C.A.), at p. 2. Given the intimate relationship between medical products and the consumer's body, and the resulting risk created to the consumer, there will almost always be a heavy onus on manufacturers of medical products to provide clear, complete and current information concerning the dangers inherent in the ordinary use of their product.

24 I pause at this point to observe that there is an important analogy to be drawn in this context between the manufacturer's duty to warn and the doctrine of "informed consent" developed by this

Court in recent years with respect to the doctor-patient relationship. In *Hopp v. Lepp*, 1980 CanLII 14 (S.C.C.), [1980] 2 S.C.R. 192, at pp. 195-96, 210, and *Reibl v. Hughes*, 1980 CanLII 23 (S.C.C.), [1980] 2 S.C.R. 880, at pp. 884-85, this Court decided that physicians have a duty, without being questioned, to disclose to a patient the material risks of a proposed procedure, its gravity, and any special or unusual risks, including risks with a low probability of occurrence, attendant upon the performance of the procedure; see also *Ciarlariello v. Schacter*, 1993 CanLII 138 (S.C.C.), [1993] 2 S.C.R. 119. The principle underlying "informed consent", as Laskin C.J. explained in *Hopp*, *supra*, at p. 196, is the "right of a patient to decide what, if anything, should be done with his body"; see also *Schloendorff v. Society of New York Hospital*, 105 N.E. 92 (N.Y.C.A. 1914), *per* Cardozo J. The doctrine of "informed consent" dictates that every individual has a right to know what risks are involved in undergoing or foregoing medical treatment and a concomitant right to make meaningful decisions based on a full understanding of those risks. As Robinson J. observed in *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972), at p. 780:

> True consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each. The average patient has little or no understanding of the medical arts, and ordinarily has only his physician to whom he can look for enlightenment with which to reach an intelligent decision. From these almost axiomatic considerations springs the need, and in turn the requirement, of a reasonable divulgence by physician to patient to make such a decision possible.

25 In my view, the principles underlying the doctrine of "informed consent" are equally, if not more, applicable to the relationship between manufacturers of medical products and consumers than to the doctor-patient relationship. The doctrine of "informed consent" was developed as a judicial attempt to redress the inequality of information that characterizes a doctor-patient relationship. An even greater relationship of inequality pertains both between the manufacturer of medical products and the consumer and, to a lesser degree, between the manufacturer and the doctor. In contrast to the doctor-patient relationship, where the patient can question the doctor with respect to the risks and benefits of particular procedures and where doctors can tailor their warnings to the needs and abilities of the individual patients, the manufacturer-consumer relationship is characterized primarily by a lack of direct communication or dialogue. This lack of dialogue between manufacturer and consumer creates, as Patricia Peppin notes in "Drug/Vaccine Risks: Patient Decision-Making and Harm Reduction in the Pharmaceutical Company Duty to Warn Action" (1991), 70 *Can. Bar Rev.* 473, at p. 474, a relationship of complete dependency between manufacturer and patient. She explains the relationship in the following terms:

> The patient is dependent both on the company and on the doctor to provide sufficient information for an informed decision to be made, as well as for treatment to heal the body, prevent a disease or palliate the pain. Dependency characterizes the relationship between vulnerable patient and the experts who exercise control over the patient's bodily fate. The physician's relationship with the pharmaceutical company also exhibits a dependency of the doctor, because of his or her limited pharmaceutical knowledge, on the company's information; but the relationship is also one in which the physician is courted through the company's marketing efforts and one in which the doctor is immune from physical harm and vulnerability.
>
> Another element of the context within which the legal principles operate is the widespread use of pharmaceutical products apparently unaccompanied by significant public knowledge of the inherent risks.

A similar observation was made by Robins J.A. in *Buchan v. Ortho Pharmaceutical (Canada) Ltd.*

1986 CanLII 114 (ON C.A.), (1986), 12 O.A.C. 361, which involved a suit by a woman against the Ortho pharmaceutical company after that woman had suffered a stroke from the use of Ortho's Novum oral contraceptives. In finding Ortho liable for failing to warn consumers about the risk of stroke inherent in the use of the contraceptives, Robins J.A. made the following observation, at p. 380:

> As between drug manufacturer and consumer, the manufacturer is a distant commercial entity that, like manufacturers of other products, promotes its products directly or indirectly to gain consumer sales, sometimes, as in this case, accentuating value while under-emphasizing risks. Manufacturers hold an enormous informational advantage over consumers and, indeed, over most physicians. The information they provide often establishes the boundaries within which a physician determines the risks of a possible harm and the benefits to be gained by a patient's use of a drug.

26 In light of the enormous informational advantage enjoyed by medical manufacturers over consumers, it is reasonable and just to require manufacturers, under the law of tort, to make clear, complete and current informational disclosure to consumers concerning the risks inherent in the ordinary use of their products. A high standard for disclosure protects public health by promoting the right to bodily integrity, increasing consumer choice and facilitating a more meaningful doctor-patient relationship. At the same time, it cannot be said that requiring manufacturers to be forthright about the risks inherent in the use of their product imposes an onerous burden on the manufacturers. As Robins J.A. explained in *Buchan, supra*, at p. 381, "drug manufacturers are in a position to escape all liability by the simple expedient of providing a clear and forthright warning of the dangers inherent in the use of their products of which they know or ought to know".

(ii) *The "Learned Intermediary" Rule*

27 As a general rule, the duty to warn is owed directly by the manufacturer to the ultimate consumer. However, in exceptional circumstances, a manufacturer may satisfy its informational duty to the consumer by providing a warning to what the American courts have, in recent years, termed a "learned intermediary". The "learned intermediary" rule was first elaborated in *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82 (8th Cir. 1966), a suit brought by a patient blinded after taking the drug chloroquine phosphate. The rationale for the rule was outlined by Wisdom J. in *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir. 1974), at p. 1276, *cert.* denied 419 U.S. 1096 (1974), a suit against a manufacturer of oral polio vaccine, in the following terms:

> Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a "learned intermediary" between manufacturer and consumer.

The rule was later reaffirmed and developed in a series of American cases during the 1970s and 1980s involving the liability of manufacturers of prescription drugs; see, for example, *Schenebeck v. Sterling Drug, Inc.*, 423 F.2d 919 (8th Cir. 1970); *Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132 (3rd. Cir. 1973); *Dunkin v. Syntex Laboratories, Inc.*, 443 F.Supp. 121 (W. D. Tenn. 1977); *Lindsay v. Ortho Pharmaceutical Corp.*, 637 F.2d 87 (2nd Cir. 1980); *Timm v. Upjohn Co.*, 624 F.2d 536 (5th Cir. 1980), *cert.* denied, 449 U.S. 1112 (1981); *Stanback v. Parke, Davis and Co.*, 657 F.2d 642 (4th Cir. 1981);

Walker v. Merck & Co., 648 F.Supp. 931 (M.D. Ga. 1986), aff'd 831 F.2d 1069 (11th Cir. 1987); *Plummer v. Lederle Laboratories*, 819 F.2d 349 (2nd Cir. 1987). In Canada, the rule was first considered in an *obiter* passage by Linden J. in *Davidson v. Connaught Laboratories* (1980), 14 C.C.L.T. 251 (Ont. H.C.), at p. 274, and later applied by a five-member panel of the Ontario Court of Appeal in *Buchan*, *supra*.

28 While the "learned intermediary" rule was originally intended to reflect, through an equitable distribution of tort duties, the tripartite informational relationship between drug manufacturers, physicians and patients, the rationale for the rule is clearly applicable in other contexts. Indeed, the "learned intermediary" rule is less a "rule" than a specific application of the long-established common law principles of intermediate examination and intervening cause developed in *Donoghue v. Stevenson*, *supra*, and subsequent cases; see, for example, *Holmes v. Ashford*, [1950] 2 All E.R. 76, at p. 80. Generally, the rule is applicable either where a product is highly technical in nature and is intended to be used only under the supervision of experts, or where the nature of the product is such that the consumer will not realistically receive a direct warning from the manufacturer before using the product. In such cases, where an intermediate inspection of the product is anticipated or where a consumer is placing primary reliance on the judgment of a "learned intermediary" and not the manufacturer, a warning to the ultimate consumer may not be necessary and the manufacturer may satisfy its duty to warn the ultimate consumer by warning the learned intermediary of the risks inherent in the use of the product.

29 However, it is important to keep in mind that the "learned intermediary" rule is merely an exception to the general manufacturer's duty to warn the consumer. The rule operates to discharge the manufacturer's duty not to the learned intermediary, but to the ultimate consumer, who has a right to full and current information about any risks inherent in the ordinary use of the product. Thus, the rule presumes that the intermediary is "learned", that is to say, fully apprised of the risks associated with the use of the product. Accordingly, the manufacturer can only be said to have discharged its duty to the consumer when the intermediary's knowledge approximates that of the manufacturer. To allow manufacturers to claim the benefit of the rule where they have not fully warned the physician would undermine the policy rationale for the duty to warn, which is to ensure that the consumer is fully informed of all risks. Since the manufacturer is in the best position to know the risks attendant upon the use of its product and is also in the best position to ensure that the product is safe for normal use, the primary duty to give a clear, complete, and current warning must fall on its shoulders.

(b) Application of the General Principles to the Case at Bar

30 The first question to be answered in this appeal is whether Dow owed Ms. Hollis a duty to warn her that the Silastic implant could rupture post-surgically inside her body and, if so, whether Dow satisfied that duty. In light of the foregoing jurisprudence, it is clear that the answer to this question depends on the answers to two subsidiary questions. First, did Dow have a duty to warn Ms. Hollis directly, or could it satisfy its duty to warn her by warning a "learned intermediary", namely, Dr. Birch? Second, assuming that Dow could properly discharge its duty to Ms. Hollis by warning Dr. Birch, did Dow adequately warn Dr. Birch of the risk of post-surgical rupture in light of its state of knowledge at that time?

31 Turning to the first of these questions, it is my view that the "learned intermediary" rule is applicable in this context, and that Dow was entitled to warn Dr. Birch concerning the risk of rupture without warning Ms. Hollis directly. A breast implant is distinct from most manufactured goods in that neither the implant nor its packaging are placed directly into the hands of the ultimate consumer. It is the surgeon, not the consumer, who obtains the implant from the manufacturer and who is therefore in the best position to read any warnings contained in the product packaging. In

this respect, breast implants are, in my view, analogous to prescription drugs, where the patient places primary reliance for information on the judgment of the surgeon, who is a "learned intermediary", and not on the manufacturer; see *Buchan*, *supra*, at p. 368. They are not analogous to oral contraceptives, with respect to which many American courts have recently imposed a direct duty to warn, because direct warnings from manufacturers of breast implants are simply not feasible given the need for intervention by a physician; see *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65 (Mass. J.C. 1985), at p. 70, *cert.* denied 474 U.S. 250 (1985); *Buchan*, *supra*, at pp. 368-69. In this respect, I observe that it is not, and has never been, Dow's practice to send warnings concerning their breast implants directly to patients. Although Dow includes product information with its implants, the implants are sold only to doctors or medical establishments, who are expected to pass this information on to their patients. In light of this fact, I conclude that a manufacturer in Dow's position can discharge its duty to the ultimate consumer by giving the treating surgeon clear, complete and current information concerning any general and specific risks that arise from the ordinary use of the product.

32 However, the mere fact that the "learned intermediary" rule is applicable in this context does not absolve Dow of liability. As I mentioned earlier, the "learned intermediary" rule presumes that the intermediary is fully apprised of the risks, and can only provide shelter to the manufacturer where it has taken adequate steps to ensure that the intermediary's knowledge of the risks in fact approximates that of the manufacturer. Thus, the second, and more important, question to be resolved is whether Dow fulfilled its duty to Ms. Hollis by adequately warning Dr. Birch of the risk of post-surgical rupture of the implant.

33 Although Bouck J. declined to rule on this issue, a majority of the Court of Appeal found that Dow's warning to Dr. Birch was inadequate. In my view, the Court of Appeal was correct in reaching this conclusion. It is well established that appellate courts have the jurisdiction to make a fresh assessment of the evidence on the record where they deem such an assessment to be in the interests of justice and feasible on a practical level; see *Prudential Trust Co. v. Forseth*, [1960] S.C.R. 210, at pp. 216-17. In this case, there was sufficient evidence on the record to allow the Court of Appeal to make a full and proper re-assessment of the duty to warn issue without sending the case back to trial. While appellate courts are generally, and justifiably, wary of making findings of fact without having the advantage of seeing and hearing testimony first-hand, I do not believe that such concerns arise in this case because the bulk of the critical evidence adduced at trial was documentary, not testimonial. In light of the fact that Ms. Hollis has now waited close to seven years for the final resolution of her claim, and the high costs already created by the unusual length of this appeal process, I believe the Court of Appeal followed the proper course in weighing and assessing this evidence in order to achieve a measure of finality in this case; see, e.g., *Davie Shipbuilding Ltd. v. The Queen*, [1984] 1 F.C. 461, at p. 464 (C.A.); *Nova, An Alberta Corporation v. Guelph Engineering Co.* reflex, (1989), 70 Alta. L.R. (2d) 97 (Alta. C.A.), at pp. 110-12.

34 Turning now to an assessment of the evidence itself, it is my view that the most compelling evidence supporting the Court of Appeal's decision can be found in the product inserts and literature which Dow supplied to doctors shortly before and after Ms. Hollis' surgery. By 1983, when Dr. Birch advised Ms. Hollis to have implantation surgery, Dow had made available to doctors two warnings regarding the risk of rupture of the Silastic implants. The first was a brochure directed at the medical community, dated 1976, and entitled "Suggested Surgical Procedures for Silastic Mammary Prostheses", which provided instructions regarding the use of the Silastic I breast implant and read as follows:

1.This prosthesis should be implanted without any alterations to its original design or fabrication. Meticulous care must be taken to avoid contact of any sharp edges or pointed objects with

the prosthesis; any inadvertent cut or puncture will expose the silicone gel and render the prosthesis unusable. Do not implant or attempt to repair and then insert a ruptured mammary prosthesis.

2.When antibiotic therapy and/or steroids (triamcinilone) are indicated, extreme care should be taken to ensure that these are delivered into the surrounding tissue and not inadvertently within the prosthesis.

. . .

5.Be certain that the patient understands that following implantation, abnormal squeezing or trauma to the breasts could conceivably rupture the implant. [Emphasis added.]

The second warning was a product insert for the Silastic implant, dated November 1979, which outlined potential problems in using the implants in the following terms:

3.If the implant should accidentally rupture during insertion or be nicked with a sharp instrument or suture needle during closure, remove the implant and replace. *Do not try to repair implant or leave in surgical pocket with torn envelope and exposed gel.*

Note

A thorough study of the information provided and the exercise of due care in handling these devices should result in no problems for the surgeon. However, since Dow Corning realizes that accidental rupture of a device can occasionally occur, it is recommended that an extra pair of the same size implants be available at the time of surgery. [Emphasis in original.]

35 It is significant that the only reference in the 1976 and 1979 warnings to a risk of post-surgical rupture was the statement that "abnormal squeezing or trauma" might rupture the implants. There is no reference in these warnings to the possibility of rupture arising from normal squeezing or non-traumatic, everyday activity. This is significant because, in 1985, Dow began warning physicians of the possibility of rupture due to normal, non-traumatic activity in the product insert for the Silastic II implant, a new breast implant developed in the early 1980s with a thicker envelope and greater durability than the earlier Silastic I model. The relevant portions of the 1985 insert read as follows:

Rupture of implants has been reported both intra- and post-operatively. Rupture may result from the following . . . excessive stresses or manipulation as may be experienced during normal living experiences including routine and purposeful trauma as in vigorous exercise, athletics, and intimate physical contact . . . or other unknown causes at the site of implantation. . . . The patient should be adequately informed of the possibility of implant rupture with the use of this technique and of the necessity to remove a ruptured implant should that occur. [Emphasis added.]

It continues with a warning about the danger of gel infection:

As reported in the literature, when an implant ruptures gel may be released from the implant envelope despite the cohesive properties of the gel. If left in place, complications such as enlarged lymph nodes, scar formation, inflammation . . . may result.

A limited preliminary study has been reported to the medical community that in the presence of select

bacterial infection at the site of a ruptured implant, extravasated gel may be altered by the bacteria with a resultant decrease in cohesivity of the gel. If true, there is greater potential for distant migration of the gel.

In the event that a ruptured prosthesis is suspected, and especially if the area becomes infected, Dow Corning recommends removal of the envelope and gel.

These potential consequences should be understood by the surgeon and explained to the patient prior to implantation.

. . .

In the event of a rupture, Dow Corning recommends prompt removal of the envelope and gel. The long term physiological effects of uncontained silicone gel are currently unknown.

. . .

Therefore, the patient should not be lead [*sic*] to unrealistic expectations as to the performance or cosmetic results that the surgery and prosthesis can provide. The patient should be informed that the life expectancy of any implant is unpredictable.

36 It is clear from a comparison of the 1985 warning with the earlier warnings that the 1985 warning is far more explicit, both with respect to the potential causes of post-surgical implant rupture and the potential effects. Of particular significance, in my view, is the statement in the 1985 warning that rupture can be caused by "excessive stresses or manipulation as may be experienced during normal living experiences" such as "vigorous exercise, athletics, and intimate physical contact". There is, without question, a substantial difference between "trauma", on the one hand, and the "stresses" and "manipulation" of "normal living experiences", on the other hand. The difference is that, while the earlier warnings implied that rupture would occur only in extreme cases of violent impact, the 1985 warning made it clear that a patient who received an implant would have to consider altering her lifestyle to avoid rupture. The difference between the 1985 warning and the earlier warnings was significant to a woman in Ms. Hollis' position because, subsequent to her surgery, she decided to enrol in a baker's course, which involved regular and heavy upper body movements. While a baker's course may not cause "trauma" to an implant, it would certainly create a risk of "excessive stresses or manipulation". Thus, a more accurate warning could quite reasonably have affected her choice of profession and her resulting exposure to unnecessary risk.

37 This is not to say, of course, that the standard of care to which Dow must be held for its warning practices in 1983 should be measured according to its knowledge of the risks of implant rupture in 1985. In light of the significant differences between the 1985 warning and the earlier warnings, the crucial next question is whether Dow knew or should have known of the risks referred to in the 1985 warning when Ms. Hollis had her implantation surgery in 1983. In my view, there was sufficient evidence adduced at trial to establish that Dow did have such knowledge. At trial, evidence was introduced that, between 1976 and 1984, Dow had received 78 field reports from doctors of post-operative "unexplained" ruptures occurring in the Silastic implants. These ruptures were categorized as "unexplained" because they were not attributable to any known causes of rupture, such as trauma or surgical mishap. The number of complaints of implant ruptures Dow received during the period 1975 to 1984 were as follows:

Year	Number of Complaints

1975	1
1976	3
1977	6
1978	5
1979	5
1980	8
1981	13
1982	7
1983	13
1984	17
Total	78

38 From the above table, it is apparent that, by late 1983, Dow had already received between 48 and 61 of the 78 unexplained rupture reports it received before issuing its revised 1985 warning. Counsel for Dow conceded that the nature and quantity of the information available to Dow did not change significantly between late 1983 and early 1985. Thus, although the reports were admitted into evidence at trial for the purpose of establishing their existence and not as to the truth of their contents, the mere fact that Dow had these reports in their possession demonstrates that, in 1983, Dow had notice that ruptures were occurring that were not directly attributable to abnormal squeezing or trauma. Counsel for Dow was unable to explain why it took Dow more than two years to convey the information concerning the unexplained ruptures to either the medical community or the consumers.

39 A similar lag time can be discerned with respect to Dow's warnings concerning the effects of implant ruptures on the body. The evidence indicates that, prior to 1983, and even as early as 1979, Dow was aware that implant ruptures could cause adverse reactions in the body arising from loose gel. In a 1979 research paper prepared by Dow's research department, the purpose of which was to determine the nature of the particulate matter produced from implants by abrasion, and to investigate possible changes in the lymph nodes and the possible transfer of the particulate material from the implant site to the lymph nodes, the department indicated the following:

> The production of particulate matter from orthopedic implants by abrasion, flexion, or other stresses is a well known and common occurrence with most prosthetic materials. The occurrence of particulate matter associated with silicone elastomer prostheses within the tissue capsule surrounding the prostheses is also known to occur.
>
> In late 1977, we were appraised [*sic*] by Dr. A. B. Swanson of two patients, both of whom had borne SILASTIC implants for several years, from whom enlarged axillary lymph nodes had been removed due to suspicion of malignancy.

The department also concluded that loose gel could travel from the implant site to the lymph nodes and could cause negative reactions:

> Thus, the intracellular material within the lymph node in all probability, has originated from the prosthetic device and appears to have produced a foreign body granulomatous inflammatory reaction within the lymph node without a significant degree of collagen proliferation. The appearance of large aggregate masses in the outer medullary regions is consistent with transport of the particulate elastomer via the lymphatic system but does not exclude concomitant vascular transport.

In light of the state of Dow's knowledge in 1979, it is significant that none of the Dow warnings before

1985 made reference to adverse reactions to loose gel in the body or the possibility that loose gel could travel away from the implant site. While the 1985 warning referred to the dangers of "enlarged lymph nodes, scar formation, inflammation" and the potential, after a rupture, for "distant migration of the gel", the 1976 and 1979 warnings make no reference to any such potential consequences.

40 In my view, Dow had a duty to convey its findings concerning both the "unexplained" rupture phenomenon and the possible harm caused by loose gel inside the body to the medical community much sooner than it did. In light of the fact that implants are surgically placed inside the human body, and that any defects in these products will obviously have a highly injurious effect on the user, the onus on Dow to be forthcoming with information was extremely high throughout the relevant period. Despite this fact, for over six years Dow took no action to express its concerns to the medical community. Given Dow's knowledge of the potential harm caused by loose gel in the body, this lag time is simply unacceptable. The duty to warn is a continuing one and manufacturers of potentially hazardous products have an obligation to keep doctors abreast of developments even if they do not consider those developments to be conclusive. As Robins J.A. noted in *Buchan*, *supra*, at p. 375:

> A manufacturer of prescription drugs occupies the position of an expert in the field; this requires that it be under a continuing duty to keep abreast of scientific developments pertaining to its product through research, adverse reaction reports, scientific literature and other available methods. When additional dangerous or potentially dangerous side-effects from the drug's use are discovered, the manufacturer must make all reasonable efforts to communicate the information to prescribing physicians. Unless doctors have current, accurate and complete information about a drug's risks, their ability to exercise the fully informed medical judgment necessary for the proper performance of their vital role in prescribing drugs for patients may be reduced or impaired.
>
> . . .
>
> . . . where medical evidence exists which tends to show a serious danger inherent in the use of a drug, the manufacturer is not entitled to ignore or discount that information in its warning solely because it finds it to be unconvincing; the manufacturer is obliged to be forthright and to tell the whole story.

41 In its submissions to this Court, Dow attempted to justify its recalcitrant warning practices by arguing that the numbers of "unexplained" ruptures were small over the relevant period (the rate of rupture was less than 1/10 of 1 percent) and by arguing that "unexplained" ruptures, being unexplained, are not a distinct category of risk of which they could realistically have warned. In my view, these arguments fail because both are based upon the assumption that Dow only had the obligation to warn once it had reached its own definitive conclusions with respect to the cause and effect of the "unexplained" ruptures. This assumption has no support in the law of Canada. Although the number of ruptures was statistically small over the relevant period, and the cause of the ruptures was unknown, Dow had an obligation to take into account the seriousness of the risk posed by a potential rupture to each user of a Silastic implant. Indeed, it is precisely because the ruptures were "unexplained" that Dow should have been concerned. Certainly, it would not have been onerous for Dow to have included an update in their product inserts to the effect that "unexplained" ruptures had been reported which were not attributable to surgical procedures, and a list of the possible side-effects of such ruptures. As Prowse J.A. observed, at pp. 20-21, of her reasons in the Court of Appeal:

> Dow was in a much better position to advise of the incidence of rupture than was any individual doctor or even the community of plastic surgeons performing breast implantations, since Dow

was the repository for complaints of rupture. This placed a significant onus on Dow to keep the medical community advised of developments with respect to its products which could have serious consequences for their patients.

. . .

Dow was not required to issue a warning each time a rupture occurred, but it would not be expecting too much to expect it to issue updated information in this regard to the medical community on a yearly basis, or sooner, if the circumstances warranted it.

42 I conclude, therefore, that the Court of Appeal made no error in ruling that Dow did not discharge its duty to Ms. Hollis by properly warning Dr. Birch concerning the risk of post-surgical implant rupture.

2. *Did Dow's Breach of the Duty to Warn Cause Ms. Hollis' Injury?*

43 Dow raises two distinct causation issues in this appeal. The first is whether Ms. Hollis would have elected to have the operation if she had been properly warned of the risk by Dr. Birch. Dow submits that a reasonable woman in Ms. Hollis' position would have consented to the surgery despite the risk and, on this basis, argues that its failure to warn was not the proximate cause of Ms. Hollis' injury. The second issue Dow raises is whether Dr. Birch would have warned Ms. Hollis if he had been properly warned by Dow of the risk. Dow submits that Ms. Hollis had the onus of establishing that Dr. Birch would not have warned Ms. Hollis even if fully apprised by Dow of the risk and, once again, argues that its failure to warn cannot be the proximate cause of her injuries. Counsel for Ms. Hollis sought to meet the first issue on a factual basis alone. As to the second issue, however, he contested as well the underpinnings of Dow's argument, which as will appear raises more substantial legal issues. I shall accordingly approach the issues on that basis.

(a)Would Ms. Hollis Have Consented to the Operation Even if Properly Warned of the Risk?

(i) *The Appropriate Test*

44 In determining whether Ms. Hollis would have consented to the operation had she been properly warned by Dr. Birch of the risk of rupture, Prowse J.A. applied the modified objective test developed by this Court in *Reibl*, *supra*, which involved a negligence action by a patient against a surgeon for failing to warn him of the risk of paralysis entailed in elective surgery performed by that surgeon. The test applied by Prowse J.A. was as follows: would a reasonable woman in Ms. Hollis' particular circumstances have consented to the surgery if she had known all the material risks? I note, however, that in *Buchan*, *supra*, at pp. 380-81, Robins J.A. found the *Reibl* test to be inapplicable to products liability cases, and instead applied a subjective test. Robins J.A.'s rationale deserves to be quoted at length:

> The considerations applicable to and the responsibilities involved in a doctor-patient relationship differ markedly from those of a manufacturer-consumer relationship. As between doctor and patient, there is a direct and intimate relationship in which the relative advantages and disadvantages of a proposed medical treatment, including the taking of a drug, can be considered, discussed and evaluated. As between drug manufacturer and consumer, the manufacturer is a distant commercial entity that, like manufacturers of other products, promotes its products directly or indirectly to gain consumer sales, sometimes, as in this case, accentuating value while under-emphasizing risks. Manufacturers hold an enormous informational advantage over consumers and, indeed, over most physicians. The information

> they provide often establishes the boundaries within which a physician determines the risks of possible harm and the benefits to be gained by a patient's use of a drug. Manufacturers, unlike doctors, are not called upon to tailor their warnings to the needs and abilities of the individual patient; and, unlike doctors, they are not required to make the type of judgment call that becomes subject to scrutiny in informed consent actions.
>
> When a manufacturer's breach of the duty to warn is found to have influenced a physician's opinion as to the safety of a drug thereby contributing to the physician's non-disclosure of a material risk and the consumer's ingestion of the drug, the manufacturer is not entitled to require the injured consumer to prove that a reasonable consumer in her position would not have taken the drug if properly warned. At this juncture, the case stands on no different footing than the usual products liability case in which there is no question of the intervention of an intermediary, and should be treated as such. The manufacturer has put a product on the market without proper warning. The likelihood that the consumer will take the drug without knowledge of its potential risks is a foreseeable consequence of the breach of the duty to warn. Whether the particular consumer would have taken the drug even with a proper warning is a matter to be decided by the trier of fact on all of the relevant evidence.
>
> . . .
>
> In my opinion, it was open to the trial judge, viewing the evidence as he did, to credit the plaintiff's testimony that she would not have taken the pill had she been told of the danger of stroke, and to determine the causation issue accordingly. Whether a so-called reasonable woman in the plaintiff's position would have done likewise is beside the point.

Robins J.A. also addressed the argument that the imposition of a subjective standard would place an undue burden on drug manufacturers. He rejected this argument for the following reason, at p. 381:

> The suggestion that the determination of this causation issue other than by way of an objective test would place an undue burden on drug manufacturers is answered by noting that drug manufacturers are in a position to escape all liability by the simple expedient of providing a clear and forthright warning of the dangers inherent in the use of their products of which they know or ought to know. In my opinion, it is sound in principle and in policy to adopt an approach which facilitates meaningful consumer choice and promotes marketplace honesty by encouraging full disclosure. This is preferable to invoking evidentiary burdens that serve to exonerate negligent manufacturers as well as manufacturers who would rather risk liability than provide information which might prejudicially affect their volume of sales.

45 In my view, the rationale given by Robins J.A. for a subjective test is compelling and justifies the adoption of the subjective test in cases of this nature. The most serious concern raised by the application of a subjective test is that the plaintiff, with the benefit of hindsight, will always claim that she would not have used the product if she had been properly warned. In *Reibl*, *supra*, at pp. 897-99, Laskin C.J. elaborated upon this concern in the following terms:

> An alternative to the subjective test is an objective one, that is, what would a reasonable person in the patient's position have done if there had been proper disclosure of attendant risks. The case for the objective standard has been tersely put in the following passage from a comment in (1973), 48 N.Y.U.L. Rev. 548, at p. 550, entitled "Informed Consent -- A Proposed Standard for Medical Disclosure":
>
> > Since proximate causation exists only if disclosure would have resulted in the patient's

> foregoing the proposed treatment, a standard must be developed to determine whether the patient would have decided against the treatment had he been informed of its risks. Two possible standards exist: whether, if informed, the particular patient would have foregone treatment (subjective view); or whether the average prudent person in plaintiff's position, informed of all material risks, would have foregone treatment (objective view). The objective standard is preferable, since the subjective standard has a gross defect: it depends on the plaintiff's testimony as to his state of mind, thereby exposing the physician to the patient's hindsight and bitterness.
>
> . . .
>
> It could hardly be expected that the patient who is suing would admit that he would have agreed to have the surgery, even knowing all the accompanying risks. His suit would indicate that, having suffered serious disablement because of the surgery, he is convinced that he would not have permitted it if there had been proper disclosure of the risks, balanced by the risks of refusing the surgery.

46 Although the concern raised by Laskin C.J. is valid and should continue to be applied in a doctor-patient relationship, in a suit against a manufacturer for failure to warn this concern can be adequately addressed at the trial level through cross-examination and through a proper weighing by the trial judge of the relevant testimony. While this difference between the type of proof required in the two kinds of actions may seem anomalous, it is amply justified having regard to the different circumstances in which the relevant duties arise, and the consequent difference in the nature of these duties. As Robins J.A. intimated in *Buchan*, the duty of the doctor is to give the best medical advice and service he or she can give to a particular patient in a specific context. It is by no means coterminous with that of the manufacturer of products used in rendering that service. The manufacturer, on the other hand, can be expected to act in a more self-interested manner. In the case of a manufacturer, therefore, there is a greater likelihood that the value of a product will be overemphasized and the risk underemphasized. It is, therefore, highly desirable from a policy perspective to hold the manufacturer to a strict standard of warning consumers of dangerous side effects to these products. There is no reason, as in the case of a doctor, to modify the usual approach to causation followed in other tortious actions. Indeed the imbalance of resources and information between the manufacturer and the patient, and even the doctor, weighs in the opposite direction. Moreover, it is important to remember that many product liability cases of this nature will arise in a context where no negligence can be attributed to a doctor. It would appear ill-advised, then, to distort the rule that is appropriate for claims against a manufacturer simply because of an apparent anomaly that results in cases where a doctor is also alleged to have been negligent.

(ii) *The Application of the Test to the Facts of the Case at Bar*

47 In my view, there was sufficient evidence adduced at trial to satisfy the subjective *Buchan* test. Ms. Hollis testified quite clearly at trial that, had she had been properly warned by Dr. Birch of the risk of rupture, she would not have had the surgery. She stated:

> Q.And what, if anything, would you have done if you had been advised that that was a risk of the procedure?
>
> A.I would not have had the procedure.
>
> Q.Why would that be?

A.Well, when I held that implant in my hand, I gave it back very quickly and it did bother me to hold it. Had I known that that gel could have escaped the bag in some way, I know I wouldn't have had the surgery.

No adverse findings were made either at trial or on appeal with respect to the credibility of Ms. Hollis' testimony.

48 Moreover, there was ample evidence adduced at trial to lend credence to Ms. Hollis' claim that she would not have had the surgery if properly warned. At trial, two plastic surgeons gave testimony concerning whether a reasonable woman in Ms. Hollis' position would have consented to the surgery if properly warned. Dow's witness was Dr. Warren, a plastic surgeon specializing in breast prosthesis implantation, who testified that "the vast majority" of women who seek breast implants "seem to come in `pre-sold'" on the idea of getting an implant. According to Dr. Warren, when the women are "pre-sold" they are not generally deterred by warnings concerning the risk of rupture. He stated:

Q.And they have obviously gone ahead and had the operation?

A.There is the occasional patient who, when they hear of these complications, decides it's not for them but certainly the vast majority -- if I can use this word -- seem to come in "presold" and they go ahead.

Dr. Birch called Dr. Thompson as a witness. Dr. Thompson is a plastic surgeon who, in the course of his practice, does breast prosthesis implantation. Under cross-examination, Dr. Thompson testified that the decision whether to have implant surgery following a proper warning will depend in large part upon the level of risk aversion to which each individual patient is susceptible. He stated:

QIn your experience with patients, is it apparent to you that some patients are risk takers and others are not risk takers?

AYes.

QSome people think nothing at all of accepting the risk of death under anaesthesia to have breast implants, when you think about it, is that correct?

AYes.

QAnd other people would single out that risk, as an example, as too great a risk to bother having breast implants?

AYes. Yes.

QAnd those judgments are different between virtually everyone in the population?

AYes.

QAnd both views are reasonable?

AYes.

49 In my view, there was ample evidence on the record to demonstrate that Ms. Hollis did not fall into the category of "pre-sold" women described by Dr. Warren. On the contrary, the evidence indicates that Ms. Hollis was not a risk taker and that she did not even consider having breast surgery until after her general practitioner, Dr. Mills, referred her for that purpose to Dr. Birch, a plastic surgeon who had been treating her for acne scarring on her cheeks. Ms. Hollis testified that, prior to her first physical exam in 1983, she had not been interested in having plastic surgery on her breasts. She stated:

A.I knew my breasts were not attractive. I might say that I became more conscious of it or self-conscious of it in my later teens.

. . .

A.I never really thought of getting them fixed. I just thought they were unattractive. I never thought of having anything done to them.

Ms. Hollis also testified that, prior to her second referral to Dr. Birch, she had never seen a doctor specifically about correcting her condition. She stated:

A.Well, it was my real first complete physical, meaning a breast examination as well, and I was nervous about it. I was nervous that I would have to show him my breast, so before -- I had a robe on and before Dr. Mills did the examination, I told him that I was self-conscious of my breasts and thought that they maybe just weren't right. And he did the examination and covered the breasts back up with the robe. And then he did say they aren't right.

. . .

A.Well, he suggested that, because I had already seen Dr. Birch about the acne pitting, that I return to him about my breasts. My right nipple was elongated as well. It almost looked like it was one and a half -- to me it looked that way.

And he said, if nothing else, Dr. Birch might be able to do something with the nipple or the nipple could have something done.

50 At trial, Dow's lawyers cross-examined Ms. Hollis persistently concerning whether she was ashamed of her breasts, whether she thought they were abnormal and whether she thought they would affect her ability to get married. Ms. Hollis admitted that she knew her breasts did not fit the "ideal" concept of an attractive breast but insisted that she was not ashamed of them. She testified:

Q.And you were concerned about what effect your appearance at that time would have on your prospects of marriage, weren't you?

A.I hadn't thought of them in that way, to that extent. I thought they were unattractive breasts and that I would live with them.

. . .

A.I looked at it more that the breasts would not be something I would have given a lot of thought to had I been in love with someone and wanted to marry. I would think that they would have been fine, even though they were unattractive.

Ms. Hollis also testified that, prior to the surgery, the appearance of her breasts had no significant effect on her social life. Her concerns about their appearance did not affect the way she wore clothing or her relationships with other people. Indeed, when asked if she had breast implant surgery to help her poor self-image, Ms. Hollis testified that her low self-esteem at that time was attributable to other factors. She stated:

> Q.I mean, you did have a poor self-image of yourself at that point, didn't you?
>
> A.I don't know if you would say poor, you know. I didn't have a wonderful self-image of myself, but, again, I'm not sure if it was simply because of my breasts.
>
> Q.Well, that was the major ingredient, if there were other factors?
>
> A.I don't know if I could even agree to that at that time.

51 The veracity of Ms. Hollis' testimony concerning this question was borne out by Dr. Birch's testimony. Dr. Birch testified that, when he originally saw Ms. Hollis to examine the acne scarring on her face, they had no discussion with respect to breast problems or a desire on her part to have breast surgery. Dr. Birch testified that it was only when Dr. Mills referred her back to him a second time that he examined her breasts. Prior to that second examination, Dr. Mills spoke to Dr. Birch, explained to him that Ms. Hollis was very shy, and told him to be gentle with her. Dr. Birch also testified that Ms. Hollis was very tentative about approaching the whole issue of the condition of her breasts. He stated:

> QNow, what was Miss Hollis' reaction or manner of presentation to you in your office on that occasion, that July 28th visit?
>
> AWell, she was as Dr. Mills had described her to be, a quiet, shy person who didn't seem to me to have easily approached this whole question of the problem she was having with her breasts. It seemed to be a very important problem to her, but she was extremely reticent in being examined so that it almost created some difficulty in carrying out an examination at first . . . .

Dr. Birch testified that Ms. Hollis was more shy than the average woman with respect to exposing her naked body. He stated:

> . . . I probably examine an average of five women a day that way and so I have some idea of what average characteristics of women's behavior in that regard are and she was not within the average at all.

Dr. Birch testified under cross-examination that the majority of his patients who have breast implants are pleased with the results. However, he felt that Ms. Hollis' case could not be compared to cases of purely cosmetic surgery in which women may be very keen to keep implants even though they may have experienced problems with them. He stated:

> QAnd the remainder that have -- that have problems with the result, is it fair to say that those people will go to lengths to attempt to keep the breast prosthesis in their body?
>
> AYes, in general I think that that's a true statement. They become happy with the increased volume. Now, we're not talking about cases like Miss Hollis, we're talking usually about cases that are just routine breast enlargement procedures.

52 I, therefore, conclude that Ms. Hollis would not have opted for the surgery had she known of all the attendant risks.

(b) Would Dr. Birch's Conduct Have Been the Same Whether or Not Dow Was in Breach of the Duty to Warn?

53 The second causation issue raised by Dow is whether Dr. Birch would have warned Ms. Hollis of the risk of rupture if Dow had properly warned Dr. Birch about that risk. Dow argues that there is no direct causal link between its breach of the duty to warn and Ms. Hollis' injury because, in 1983, Dr. Birch was aware of the risk of implant rupture but did not make a habit of warning his patients about that risk. In support of this argument, Dow relies on Dr. Birch's testimony at trial that, in 1983, he was warning only 20% to 30% of his patients of implant rupture, and that, in determining the nature and scope of his warnings to patients, he relied more on the articles he read in medical journals than on manufacturers' warnings.

54 It is right to say, however, that the trial judge found that in 1983 the average plastic surgeon in British Columbia did not in fact know about the possibility that rupture of Silastic implants could be a factor of any significance. This finding is supported and amplified by the fact that after Dow began circulating its more extensive 1985 warning and knowledge of the risk of rupture in the medical community became more prevalent, Dr. Birch adapted his practice accordingly, and by 1989 he was warning all his patients of the risk of rupture.

55 I do not propose to enter further into or assess these factors. I say this because, while Dow is correct in submitting that there was some ambiguity at trial concerning Dr. Birch's warning practices in 1983, Dow's argument is based upon the assumption that to succeed in her claim against Dow Ms. Hollis must prove that Dr. Birch would have warned her if Dow had properly warned Dr. Birch. I do not think this assumption is well founded. Ms. Hollis, it will be remembered, demonstrated that Dow had breached its duty to warn her of the risk of rupture, that she would not have undergone the medical procedure if she had been fully informed of the risks, and that she suffered injury from the rupture. Had Dr. Birch been adequately warned but had not passed on the information to Ms. Hollis, Dow would, it is true, have been absolved of liability by virtue of the learned intermediary doctrine. But I fail to see how one can reason from this that, for Dow to be liable, Ms. Hollis must now establish that Dr. Birch would have informed her if he had known. To require her to do so would be to ask her to prove a hypothetical situation relating to her doctor's conduct, one, moreover, brought about by Dow's failure to perform its duty. While the legal and persuasive onus in a negligence case generally falls on the plaintiff, I do not see how this can require the plaintiff to prove a hypothetical situation of this kind.

56 The reasoning in this Court's decision in *Cook v. Lewis*, 1951 CanLII 1 (S.C.C.), [1951] S.C.R. 830, is helpful in this context. In that case, the plaintiff was shot by one of two members of a hunting party. The jury had found that the plaintiff had been shot by one of the two hunters, and that both of the hunters had been negligent in shooting in the plaintiff's direction, but were unable to say which hunter's bullet had actually hit the plaintiff. On this basis, the jury exculpated both defendants from negligence. This Court set aside the jury finding and ruled that, once the plaintiff had proved that he had been shot by one of the defendants, the onus was on the defendants to establish absence of negligence. Unless they could exculpate themselves both would be liable. In a concurring judgment setting forth his reasons for reversing the burden of proof, Rand J. made the following remarks, at pp. 832-33, that serve to illuminate the present discussion:

> What, then, the culpable actor has done by his initial negligent act is, first, to have set in motion

> a dangerous force which embraces the injured person within the scope of its probable mischief; and next, in conjunction with circumstances which he must be held to contemplate, to have made more difficult if not impossible the means of proving the possible damaging results of his own act or the similar results of the act of another. He has violated not only the victim's substantive right to security, but he has also culpably impaired the latter's remedial right of establishing liability. By confusing his act with environmental conditions, he has, in effect, destroyed the victim's power of proof.
>
> The legal consequence of that is, I should say, that the onus is then shifted to the wrongdoer to exculpate himself; it becomes in fact a question of proof between him and the other and innocent member of the alternatives, the burden of which he must bear. The onus attaches to culpability, and if both acts bear that taint, the onus or prima facie transmission of responsibility attaches to both, and the question of the sole responsibility of one is a matter between them. [Emphasis added.]

57 In my view, a close analogy can be drawn between *Cook* and the case at bar. The facts on the record demonstrate that Ms. Hollis was inadequately warned of the possibility that the breast implants manufactured by Dow and surgically implanted by Dr. Birch could rupture. While the victim's power of proof has not been destroyed in the same sense as in the hunting party case, it has been seriously undermined in that the plaintiff is, on Dow's contention, called upon to prove what a doctor would have done in a hypothetical situation. It must be kept in mind that the governing principle in a case of this nature is informed consent, namely, the right of the patient to be fully informed by the manufacturer of all material risks associated with the use of a medical product. It is clear from the record that Ms. Hollis' right to informed consent was not respected in this case. We know that Dow's failure to warn was a cause of her injury; whether Dr. Birch's actions in the hypothetical situation posited by Dow might also have been a cause is not a matter for Ms. Hollis to prove. Ms. Hollis, who was in a position of great informational inequality with respect to both the manufacturer and the doctor, played no part in creating the set of causal conditions leading to her injury. Justice dictates that she should not be penalized for the fact that had the manufacturer actually met its duty to warn, the doctor still might have been at fault.

58 I observe that the Ontario Court of Appeal in *obiter* in *Buchan*, *supra*, has adopted a somewhat similar approach to causal analysis in cases of this nature. There Robins J.A. had this to say, at p. 377:

> Once the breach of duty to warn prescribing physicians has been established, I think it fair and reasonable to presume that the inadequacy of the warning was a contributing cause of the ingestion of the drug. It ought not to be incumbent on a plaintiff to prove as part of her case what her doctor might or might not have done had he been adequately warned. One can assume that a doctor would not ignore a proper warning or fail to disclose a material risk or otherwise act negligently. Even if the evidence were to indicate that the doctor was negligent, the manufacturer would not be shielded from liability if such negligence were a foreseeable consequence of the breach of duty to warn. The presumption may, of course, be rebutted if the defendant comes forth with evidence that despite the inadequacy of the warning the doctor's conduct toward his patient would have been the same whether or not the manufacturer was in breach of the duty. [Emphasis added.]

59 In the last sentence of this statement, Robins J.A. refers to the possibility that the manufacturer might be able to adduce evidence that the doctor's conduct might have been the same whether or not the manufacturer was in breach of its duty. I should say that whatever effect this may have regarding the apportionment of liability between the doctor and the manufacturer in the event that

the doctor is also found to be negligent, it in no way absolves the manufacturer from liability to the plaintiff, except in cases where some extraneous conduct by the doctor would have made the failure to give adequate warning irrelevant. But that is not this case. In sum, in a case like the present, I see no reason why in establishing the liability of the manufacturer the law should adopt a rule requiring the plaintiff to delve into what the doctor might have done.

60 Simply put, I do not think a manufacturer should be able to escape liability for failing to give a warning it was under a duty to give, by simply presenting evidence tending to establish that even if the doctor had been given the warning, he or she would not have passed it on to the patient, let alone putting an onus on the plaintiff to do so. Adopting such a rule would, in some cases, run the risk of leaving the plaintiff with no compensation for her injuries. She would not be able to recover against a doctor who had not been negligent with respect to the information that he or she did have; yet she also would not be able to recover against a manufacturer who, despite having failed in its duty to warn, could escape liability on the basis that, had the doctor been appropriately warned, he or she still would not have passed the information on to the plaintiff. Our tort law should not be held to contemplate such an anomalous result.

61 As I see it, the plaintiff's claim against the manufacturer should be dealt with in accordance with the following rationale. The ultimate duty of the manufacturer is to warn the plaintiff adequately. For practical reasons, the law permits it to acquit itself of that duty by warning an informed intermediary. Having failed to warn the intermediary, the manufacturer has failed in its duty to warn the plaintiff who ultimately suffered injury by using the product. The fact that the manufacturer would have been absolved had it followed the route of informing the plaintiff through the learned intermediary should not absolve it of its duty to the plaintiff because of the possibility, even the probability, that the learned intermediary would not have advised her had the manufacturer issued it. The learned intermediary rule provides a means by which the manufacturer can discharge its duty to give adequate information of the risks to the plaintiff by informing the intermediary, but if it fails to do so it cannot raise as a defence that the intermediary could have ignored this information. I observe that a number of courts in the United States have reached a similar conclusion. In *McCue v. Norwich Pharmacal Co.*, 453 F.2d 1033 (1st Cir. 1972), at p. 1035, for example, the Court of Appeal for the First Circuit stated:

> Even if a physician's carelessness may have taken a form not specifically anticipated, defendant should not escape liability so long as its failure to give an adequate warning may have contributed thereto . . . . [H]aving put a dangerous drug on the market without adequate warning defendant cannot be heard to say that the physician might have disregarded a proper one. [Emphasis added.]

See also *Sterling*, *supra*, and *Hamilton v. Hardy*, 549 P.2d 1099 (Colo. C.A. 1976).

Conclusion

62 On the basis of the foregoing, it is my view that Dow breached its duty to warn Dr. Birch concerning the risks of post-surgical rupture in the Silastic implant and because of this failure to warn is liable to Ms. Hollis for her injuries. Accordingly, I would dismiss the appeal.

63 Ms. Hollis is entitled to her costs throughout.

The reasons of Sopinka and McLachlin JJ. were delivered by

64 SOPINKA J. (dissenting) -- I agree with Justice La Forest in his analysis of the principles relating to the duty to warn and in particular that the learned intermediary principles apply as he

proposes. I respectfully disagree, however, with his analysis and application of the principles relating to causation. In my view the so-called subjective test is inappropriate to determine whether Ms. Hollis would have consented to the operation if properly warned. In addition, I cannot agree that Ms. Hollis need not prove that any warning received by Dr. Birch would have been passed along by the doctor to his patients. Finally, I disagree that this Court is in a position to resolve factual issues which were not addressed at trial and which are vital to a determination of the liability of Dow. In my opinion a new trial is necessary to resolve these issues by reason of:

(1) the settled practice of appellate courts not to make findings of fact that were not made at trial in the circumstances of this case;

(2) the finding of fact with respect to whether Ms. Hollis would not have consented to the operation if properly warned will trump this issue in the new trial relating to the liability of Dr. Birch;

(3) a finding of liability of Dow in this Court will make it extremely difficult or impossible for the trial judge to assess the degrees of fault of Dow and Dr. Birch.

Analysis

Causation

The Test

65 In his reasons, La Forest J. adopts a subjective test to determine whether Ms. Hollis would have consented to the operation if properly warned. In this regard, he adopts the reasoning of Robins J.A. in *Buchan v. Ortho Pharmaceutical (Canada) Ltd.* 1986 CanLII 114 (ON C.A.), (1986), 12 O.A.C. 361. In reviewing the evidence to determine if there "was sufficient evidence adduced at trial to satisfy the subjective *Buchan* test" (para. 47), however, he refers to the evidence of experts which is only relevant in applying a reasonable woman test. He concludes, at para. 52, that "Ms. Hollis would not have opted for the surgery".

66 In determining that Ms. Hollis would not have opted to undergo the implantation, my colleague refers to the evidence of experts in the field of breast implant surgery. In support of his position, La Forest J. (at para. 48) relies on the evidence of two plastic surgeons who "gave testimony concerning whether a reasonable woman in Ms. Hollis' position would have consented to the surgery if properly warned". The *Buchan* subjective test, however, places no reliance on evidence as to what a reasonable woman would do. The exposition of the subjective test which my colleague adopts is set out in the following passage from *Buchan*, at p. 381, part of which is reproduced in La Forest J.'s decision:

> In my opinion, it was open to the trial judge, viewing the evidence as he did, to credit the plaintiff's testimony that she would not have taken the pill had she been told of the danger of stroke, and to determine the causation issue accordingly. Whether a so-called reasonable woman in the plaintiff's position would have done likewise is beside the point. The selection of a method of preventing unwanted pregnancy in the case of a healthy woman is a matter, not of medical treatment, but of personal choice; and it is not unreasonable that notice of a serious potential hazard to users of oral contraceptives could influence her selection of another method of birth control. So long as the court is satisfied that the plaintiff herself would not have used the drug if properly informed of the risks, this causation issue should be concluded in her favour regardless of what other women might have done. [Emphasis added.]

67 The *Buchan* subjective approach fails to take into account the inherent unreliability of the plaintiff's self-serving assertion. It is not simply a question as to whether the plaintiff is believed. The plaintiff may be perfectly sincere in stating that in hindsight she believed that she would not have consented to the operation. This is not a statement of fact that, if accepted, concludes the matter. It is an opinion about what the plaintiff would have done in respect of a situation that did not occur. As such, the opinion may be honestly given without being accepted. In evaluating the opinion, the trier of fact must discount its probity not only by reason of its self-serving nature, but also by reason of the fact that it is likely to be coloured by the trauma occasioned by the failed procedure. For this reason, the most reliable approach in determining what would in fact have occurred is to test the plaintiff's assertion by reference to objective evidence as to what a reasonable person would have done. The matter is aptly summarized by the Supreme Court of California in *Cobbs v. Grant*, 502 P.2d 1 (1972). At pp. 11-12, they held:

> The patient-plaintiff may testify on this subject but the issue extends beyond his credibility. Since at the time of trial the uncommunicated hazard has materialized, it would be surprising if the patient-plaintiff did not claim that had he been informed of the dangers he would have declined treatment. Subjectively he may believe so, with the 20/20 vision of hindsight, but we doubt that justice will be served by placing the physician in jeopardy of the patient's bitterness and disillusionment. Thus an objective test is preferable: i. e., what would a prudent person in the patient's position have decided if adequately informed of all significant perils.

This was the test adopted by this Court in *Reibl v. Hughes*, 1980 CanLII 23 (S.C.C.), [1980] 2 S.C.R. 880, which was followed by Prowse J.A. for the majority in the Court of Appeal. In *Reibl*, Laskin C.J. stated, at p. 898:

> It could hardly be expected that the patient who is suing would admit that he would have agreed to have the surgery, even knowing all the accompanying risks. His suit would indicate that, having suffered serious disablement because of the surgery, he is convinced that he would not have permitted it if there had been proper disclosure of the risks, balanced by the risks of refusing the surgery. Yet, to apply a subjective test to causation would, correlatively, put a premium on hindsight, even more of a premium than would be put on medical evidence in assessing causation by an objective standard. [Emphasis added.]

Laskin C.J. went on, however, to stress at p. 900 that the patient's testimony is essential but "it must be objectively assessed in terms of reasonableness".

68 In Laskin C.J.'s view, this was the most reliable way to answer the question as to what would have occurred. This answers the concern of Robins J.A. that the plaintiff's choice must be respected. The *Reibl* approach is a more reliable method of determining what that choice would have been. The subjective test places too much of a premium on the plaintiff's present belief as to what it would have been. Assuming that it is in fact the *Buchan* subjective test that my colleague advocates, expert medical evidence as to what a reasonable woman would do is, to use the words of Robins J.A. at p. 381, "beside the point". La Forest J.'s apparent need to bolster Ms. Hollis' testimony by reference to such expert evidence clearly demonstrates the inherent weakness of the *Buchan* subjective test. As a result of this weakness, I would reject the subjective test in favour of the approach adopted in *Reibl*.

69 Moreover, I see no reason why the test for determining the same issue should be different for the physician and the manufacturer. With respect to both, the question for the plaintiff is the same. How would the plaintiff have responded if properly warned by the physician? Is the trial judge to apply two different tests to determine the same question? If so, this could conceivably result in a

finding that, *vis-à-vis* the physician, the patient would have consented, and *vis-à-vis* the manufacturer, she would not. Indeed, in the new trial which has been directed by the Court of Appeal with respect to Dr. Birch, the trial judge is obliged to apply the *Reibl* test and may very well find that Ms. Hollis would have agreed to the implant if properly warned.

70 I fail to understand how a different test for the physician and the manufacturer, which, my colleague acknowledges, seems anomalous, can be redeemed on the basis that a stricter standard can be expected of the manufacturer. This ignores the fact we are dealing with a situation in which the manufacturer's duty to the plaintiff is discharged by informing the physician of risks. The physician is expected to pass this on to the patient. If the risk is one about which the plaintiff ought to be warned, it can hardly be suggested that the physician can water down the warning because a lower standard applies to the physician. One could, perhaps, talk about a different standard when comparing the respective duties to warn when the learned intermediary rule does not apply and both the physician and manufacturer have a duty to warn the plaintiff directly. However, when the duties of the manufacturer and the physician to warn the plaintiff are to be discharged by virtue of the information received from the manufacturer being passed on to the plaintiff and both the physician and manufacturer are sued in one action for breach of that duty, there is no room for the application of a different standard. Indeed, the issue of causation has nothing to do with the standard of disclosure. In resolving this issue, the Court attempts to determine what the plaintiff's response would have been on the assumption that the appropriate warning has been given in accordance with the appropriate standard. The debate concerns the bases on which that response should be measured, not about the standard of disclosure.

71 But, whether the subjective or objective test is adopted, it is a difficult question of fact which should be determined at trial and not on appeal. I will return to this later in these reasons.

Burden of Proof

72 In determining the second causation issue of whether Dr. Birch would have warned Ms. Hollis of the risk of rupture if Dow had properly warned Dr. Birch about that risk, La Forest J. proposes to eliminate the fundamental requirement of tort law that the plaintiff establish causation in order to prove the defendant's liability. Once Ms. Hollis demonstrated that Dow had breached its duty to warn of the risk of rupture, La Forest J. would hold that the plaintiff's burden of proving her case had been discharged, and that any possibility that Dr. Birch would have failed to pass on any warning is nothing more than a question of apportionment. This approach runs counter to well established tort principles. Simply put, in order to establish liability, the plaintiff must show not only a breach of duty by the defendant, but also that the breach in question was the cause of the plaintiff's injury.

73 In the instant case, this burden applies to require the plaintiff to show that her injuries would not have occurred had Dow discharged its duty to warn Dr. Birch of any dangers inherent in the implants. In other words, Ms. Hollis must show that her doctor would have warned her of any dangers that had been brought to his attention and that if warned she would have refused the operation. Absent this form of proof, it cannot be said with any degree of certainty that the failure of Dow to warn physicians was the cause of the unfortunate injuries suffered by Ms. Hollis.

74 Professor John G. Fleming, in *The Law of Torts* (8th ed. 1992), at p. 143, explains the necessity of a factual finding of a cause and effect relationship between the defendant's breach of duty and the plaintiff's injury as follows:

If such a causal relation does not exist, that puts an end to the plaintiff's case: to impose liability for loss to

> which the defendant's conduct has not *in fact* contributed would be incompatible with the principle of individual responsibility on which the law of torts has been traditionally based. [Emphasis in original.]

75 If Dr. Birch would not have passed on information from Dow to Ms. Hollis, Dow's failure to provide the warning cannot be said to have contributed to Ms. Hollis' injury. Liability cannot be based on failure to take measures which would have no effect and be pointless.

76 The absence of cause cannot be finessed by sweeping it under the apportionment rug as suggested by my colleague. A finding of causation is a prerequisite to apportionment. Apportionment is authorized only in the circumstances mandated by the *Negligence Act*, R.S.B.C. 1979, c. 298, where the damage or loss is caused by the fault of two or more persons.

77 My colleague refers to a number of cases, such as *Cook v. Lewis*, 1951 CanLII 1 (S.C.C.), [1951] S.C.R. 830, *Snell v. Farrell*, 1990 CanLII 70 (S.C.C.), [1990] 2 S.C.R. 311, and *Buchan*, *supra*, which either reversed or relaxed the ordinary burden which rests on the plaintiff to prove causation. Those cases do not support treating causation as irrelevant. Indeed, they start with the premise that causation is a fundamental principle and address whether the plaintiff's ordinary burden should be eased. Not only is the requirement that causation be established fundamental to the law of torts, but, as well, the principle that the burden of proof of causation generally rests with the plaintiff is also well entrenched. The House of Lords in *McGhee v. National Coal Board*, [1973] 1 S.L.T.R. 14, toyed with the notion that the burden should be reversed in certain circumstances. On further consideration, however, this approach was firmly rejected in *Wilsher v. Essex Area Health Authority*, [1988] A.C. 1074. In none of the foregoing cases was it suggested that the problem could be avoided by treating the issue of causation as irrelevant. I propose, however, to discuss the cases to which my colleague refers because they either do not support the reversal of the burden of proof or, if they did, that would not resolve the issue of causation in this case.

78 My colleague refers to the judgment of this Court in *Cook v. Lewis*, *supra*. In that appeal, the plaintiff hunter had been shot in the face by bird-shot. Two defendants admitted to having discharged their guns in the vicinity of the plaintiff at almost the same time, but not at the same bird. In that case, this Court determined that the plaintiff's need to prove causation could be obviated by reversing the ordinary burden of proof in certain situations. According to the Court in *Cook*, the reversal of the burden was appropriate in that case because the defendants had essentially removed the means of proof of causation from the plaintiff. As Rand J. stated, at p. 832:

> What, then, the culpable actor has done by his initial negligent act is, first, to have set in motion a dangerous force which embraces the injured person within the scope of its probable mischief; and next, in conjunction with circumstances which he must be held to contemplate, to have made more difficult if not impossible the means of proving the possible damaging results of his own act or the similar results of the act of another. He has violated not only the victim's substantive right to security, but he has also culpably impaired the latter's remedial right of establishing liability. By confusing his act with environmental conditions, he has, in effect, destroyed the victim's power of proof. [Emphasis added.]

Since the "negligent actor ha[d] culpably participated in the proof-destroying fact", the burden of proof was reversed (at p. 835), and the plaintiff was relieved of the need to prove direct causation.

79 Similarly, this Court in *Snell v. Farrell*, *supra*, at p. 321, expressed the view that the burden on the plaintiff could be reversed where the subject matter of the alleged tortious conduct lies "particularly within the knowledge" of the defendant. In *Snell*, the defendant surgeon had removed

a cataract from the patient plaintiff's eye and the patient had later lost her sight in that eye as a result of optic nerve atrophy. The defendant doctor, knowing what he had done, was in a significantly better position to determine what had occurred. In the reasons for judgment for a unanimous Court, the grounds for reversing the burden of proof with respect to causation were stated at pp. 326-27:

> If I were convinced that defendants who have a substantial connection to the injury were escaping liability because plaintiffs cannot prove causation under currently applied principles, I would not hesitate to adopt one of these alternatives. In my opinion, however, properly applied, the principles relating to causation are adequate to the task. Adoption of either of the proposed alternatives would have the effect of compensating plaintiffs where a substantial connection between the injury and the defendant's conduct is absent. Reversing the burden of proof may be justified where two defendants negligently fire in the direction of the plaintiff and then by their tortious conduct destroy the means of proof at his disposal. In such a case it is clear that the injury was not caused by neutral conduct. It is quite a different matter to compensate a plaintiff by reversing the burden of proof for an injury that may very well be due to factors unconnected to the defendant and not the fault of anyone.

80 As a result, the burden of proof is properly reversed where the defendant has somehow participated in destroying the means of proving the case against it or where the defendant somehow controls the relevant evidence. Only within this limited sphere of cases is the plaintiff partially relieved of the burden of proving causation. In this case, there is neither any suggestion of a tortious destruction of the means of proof nor does the evidence lie peculiarly in the control of the defendant Dow. On the contrary, the issue in question is largely dependent on the evidence of Dr. Birch. Both Ms. Hollis and Dow have equal access to the evidence of Dr. Birch. Indeed, in this situation, the physician is likely to be inclined to favour his patient, the plaintiff. It is not in the interests of the physician to assert that he would not have passed on a warning that the manufacturer was duty-bound to give him for the benefit of the plaintiff. As the means of proving causation remains available to the plaintiff, it would be inconsistent with *Snell* to reverse the burden of proof. As a result, the burden of proving causation remains on the plaintiff in this case. In order to discharge the burden in question, the plaintiff must adduce evidence that her doctor would have warned her of any dangers associated with breast implants had those dangers been brought to his attention by the defendant.

81 An alternative method of obviating the plaintiff's burden of proof was suggested by the Court of Appeal in *Buchan*. In that case, the court expressed the view that a "rebuttable presumption" exists such that a plaintiff in Ms. Hollis' position need not establish all elements of causation. According to the court, at p. 377:

> Once the breach of duty to warn prescribing physicians has been established, I think it fair and reasonable to presume that the inadequacy of the warning was a contributing cause of the ingestion of the drug. It ought not to be incumbent on a plaintiff to prove as part of her case what her doctor might or might not have done had he been adequately warned. One can assume that a doctor would not ignore a proper warning or fail to disclose a material risk or otherwise act negligently. Even if the evidence were to indicate that the doctor was negligent, the manufacturer would not be shielded from liability if such negligence were a foreseeable consequence of the breach of duty to warn. The presumption may, of course, be rebutted if the defendant comes forth with evidence that despite the inadequacy of the warning the doctor's conduct toward his patient would have been the same whether or not the manufacturer was in breach of the duty.

Based on this approach, the plaintiff need not prove that her doctor would have warned her of any dangers

unless the defendant presents some evidence tending to show that the doctor may not have in fact passed along the appropriate warning. The burden on the defendant is discharged where sufficient evidence is adduced to raise the issue of causation. This is an "evidential" burden of proof, which has been described by Professor Tapper in *Cross on Evidence* (7th ed. 1990), at p. 113, as:

> . . . the obligation to show, if called upon to do so, that there is sufficient evidence to raise an issue as to the existence or non-existence of a fact in issue, due regard being had to the standard of proof demanded of the party under such obligation.

Thus, the rebuttable presumption referred to in *Buchan* merely requires the defendant to furnish sufficient proof to raise a question of whether or not the "learned intermediary" would have passed a warning along had one been provided by the manufacturer. Where this nominal burden has been discharged, the ultimate burden of proving causation remains on the plaintiff, requiring her to show that any warnings received by Dr. Birch would have been passed along.

82 If the burden of proof were reversed as proposed in *Cook v. Lewis*, it would not operate against the defendant if there was sufficient evidence to raise the issue of causation. In that event, the trier of fact would be obliged to weigh the evidence. The burden of proof would only be applied if the trier of fact were unable to come to a determinate conclusion. See *Cross on Evidence*, *supra*, at pp. 112-13, and *McCormick on Evidence* (3rd ed. 1984), at p. 947.

83 Whether one applies the presumption in *Buchan* or reverses the burden of proof as in *Cook v. Lewis*, I am of the view that there was abundant evidence in this case to raise the issue and it was conflicting. My colleague has reviewed some of this evidence. I agree with Bouck J.'s finding that the possibility of rupture of gel-filled implants, including the risk of rupture owing to trauma or abnormal squeezing, was not well known to the medical community in July-October 1983 when Ms. Hollis consulted Dr. Birch and he performed the surgery. The only apparent warning received by Dr. Birch concerned ruptures resulting from abnormal trauma, and contained the following statement:

> 5.Be certain that the patient understands that following implantation, abnormal squeezing or trauma to the breasts could conceivably rupture the implant.

84 Dr. Birch failed to warn Ms. Hollis and it was not his habit to warn patients of the risk of rupture due to trauma or abnormal squeezing because he did not regard it as a common occurrence. In this regard, he relied primarily on medical literature and not the manufacturer's literature. He testified as follows:

> Q.I'm going to point number five, do you see that? It says:
>
> "Be certain that the patient understands that following implantation, abnormal squeezing or trauma to the breast could conceivably rupture the implant."
>
> Doctor, do --
>
> A. Yes.
>
> Q.-- you see that. Now, doctor, you don't rely on the manufacturers' literature, though, with respect to these particular products, do you?
>
> A.No. I rely more on the medical literature.

85 Counsel for Ms. Hollis relies heavily on the 1985 warning as evidence of the type of warning that Dow had a duty to give in 1983. My colleague accepts this as significant evidence as to the type of warning that should have been given. There is cogent evidence in the record that if this warning had been given to Dr. Birch in 1983, he would not necessarily have passed it on. In October 1987, two years after Dr. Birch had received the 1985 warning referred to above, it was still not his practice to pass the warning on to patients. Examined for discovery in October 1987, he gave the following evidence:

QIs that your practice now to do that, to discuss the possibility of rupture of prosthesis?

ANot usually.

86 While by 1989 he was warning all his patients of the risk of rupture, at trial he could not say "[w]hen it became more than 50 per cent". This is consistent with his testimony that he relied more upon the state of medical knowledge and medical literature than upon manufacturers' literature. This evidence might very well have been accepted by the trial judge if he had considered this issue. In my view, if my colleague had referred to this evidence, he could not have concluded but that there was ample evidence to raise the issue.

87 Accordingly, if this issue had been addressed at trial, the trial judge would have been obliged to weigh the evidence in order to resolve the conflict. The burden of proof would play no part in this determination. Only if the evidence were so evenly balanced that a determinate conclusion could not be reached would resort to the legal burden of proof have been necessary. The weighing of conflicting evidence is vital in the resolution of any factual issue in respect of which the evidence is in conflict. This did not occur at trial here. Prowse J.A., in her majority judgment, did not weigh the evidence because she concluded that Dow had a duty to warn Ms. Hollis directly. As a result, this aspect of causation did not arise. My colleague does not weigh the evidence because he largely dispenses with the need to prove causation. The result is that this fundamental step in the trial process which is so important in resolving factual disputes will have been by-passed if a new trial is not directed. I now turn to address that issue more specifically.

A New Trial is Necessary

88 The issue in this case is not the right of an appellate court to review findings of fact made at trial or what standard governs such review. The issue is what approach should a court of appeal adopt when disposing of an appeal on a legal basis that was not dealt with or resolved at trial, where crucial findings of fact concerning that issue were not made by the trial judge. In the former case, the trial judge has addressed the factual question with which the appellate court should not interfere or substitute its own decision unless the appellate court can identify why the trial judge's conclusions are clearly wrong. The parties, however, have had the factual issue considered. The claim to a new trial in such circumstances is less compelling by reason of the fact that the factual issues have been weighed at trial. If the court of appeal can identify where the trial judge was clearly wrong, there is less concern that the parties are deprived of the advantage of having had at least one assessment of the facts. The appellate court can correct clear error with the background of that assessment. Nevertheless, findings of credibility and conflicts in the evidence that are dependent on the advantages of seeing and hearing the witness are generally exceptions to the exercise of the power of an appellate court to substitute its findings for those of the trial judge. This applies even if the conflict is between expert witnesses. Moreover, even when an appellate court exercises the power to interfere with the findings, the usual order is to direct a new trial if the nature of the evidence is such that there is an advantage in hearing and seeing the witnesses.

89 In contrast, in a case in which a trial judge fails to make factual findings which are essential to resolve an issue, a court of appeal is extremely reluctant to assume the role of the trial judge. In such circumstances, it is more hazardous to venture an opinion that the trial judge would not have had an advantage when there has been no demonstration as to how the trial judge availed himself or herself of the advantage. More importantly, there is considerable support for the view that the party affected is entitled to a new trial virtually as of right. In *Just v. British Columbia*, 1989 CanLII 16 (S.C.C.), [1989] 2 S.C.R. 1228, this Court reversed the Court of Appeal which had affirmed the judgment at trial dismissing the plaintiff's action. The trial judge classified certain practices of the government agency as policy rather than operational and therefore exempt from liability. Although these practices and their deficiencies were fully explored in the evidence presented at trial, this Court nevertheless ordered a new trial. Speaking for the majority, Cory J. stated, at pp. 1246-47:

> At trial the conclusion was reached that the number and frequency of inspections, of scaling and other remedial measures were matters of policy; as a result no findings of fact were made on the issues bearing on the standard of care. Since the matter was one of operation the respondent was not immune from suit and the negligence issue had to be canvassed in its entirety. The appellant was therefore entitled to a finding of fact on these questions and a new trial should be directed to accomplish this.
>
> . . .
>
> To proceed in this way is fair to both the government agency and the litigant. Once a duty of care that is not exempted has been established the trial will determine whether the government agency has met the requisite standard of care. At that stage the system and manner of inspection may be reviewed. However, the review will be undertaken bearing in mind the budgetary restraints imposed and the availability of personnel and equipment to carry out such an inspection.

90 Similarly, in *Koschman v. Hay* (1977), 17 O.R. (2d) 557 (C.A.), in an appeal in which the trial judge had failed to resolve conflicts in the evidence, Lacourcière J.A. stated, at p. 558:

> The vital importance of reasons for judgment in such cases cannot be over-emphasized. This Court cannot decide issues of fact on the bald record. The parties are entitled to the findings of the trial Judge on disputed evidence, and an appellate Court cannot properly exercise its function without them. I refer to a decision of this Court in *DeJussel et al. v. Hajzer*, [1948] O.W.N. 468, and to *Wright and Wright v. Ruckstuhl*, [1955] O.W.N. 32, [1955] 2 D.L.R. 77, where Chief Justice Pickup, speaking for the Court, expressed this principle in no uncertain terms. This Court has never departed from that principle. We are, therefore, unanimously forced to conclude that the assessment of the plaintiffs' damages must be sent back for a new trial.

91 La Forest J. in *Chan v. Canada (Minister of Employment and Immigration)*, 1995 CanLII 71 (S.C.C.), [1995] 3 S.C.R. 593, identifies the difficulty which an appellate court faces in assessing factual issues when the trier of fact has failed to do so. He states, at para. 45:

> A reviewing court must, in assessing a Board's factual decision, attempt to put itself in its position. This can pose serious difficulties where the Board has made no finding on a critical issue but has simply disposed of the matter on the basis of a legal finding.

92 Courts have departed from this established practice in exceptional circumstances in which the appellate court is able to conclude that it is in as good a position to resolve the issue as the trial judge. In such circumstances, there is no special advantage in remitting the matter back to the trial judge, and the party affected is not prejudiced thereby. A material consideration is that a final resolution of the case will avoid a new trial.

93 Circumstances that permit the conclusion to be drawn that the appellate court is in as good a position as the trial judge and that no advantage is lost include:

(i)the trial judge has made the necessary findings albeit in respect of a different legal issue, or it can be safely assumed from findings actually made that but for the error of law the necessary findings would have been made;

(ii)the evidence is not in dispute or conflict and no issue of credibility is involved;

(iii)special circumstances exist in which the parties urge the appellate court to make necessary findings of fact.

See *Snell v. Farrell, supra*; *Davie Shipbuilding Ltd. v. The Queen*, [1984] 1 F.C. 461 (C.A.); *Jardine v. Northern Co-operative Timber and Mill Association*, [1945] 1 W.W.R. 533 (B.C.C.A.); *Nova, An Alberta Corporation v. Guelph Engineering Co.* reflex, (1989), 70 Alta. L.R. (2d) 97.

94 Cases in which this power has been exercised have stressed that it should only be resorted to in "unique" circumstances (*Nova*, at p. 112) and with extreme care to ensure that "such a course will . . . do complete justice between the parties" (*Glow v. Paquin*, [1932] 1 W.W.R. 737 (Man. C.A.), at p. 742). As a result, the preferred course of action is to order a new trial. See *Patterson v. Township of Aldborough* (1913), 11 D.L.R. 437 (Ont. C.A.); *Colautti Construction Ltd. v. City of Ottawa* (1984), 9 D.L.R. (4th) 265 (Ont. C.A.); *Bank of Nova Scotia v. Dunphy Leasing Enterprises Ltd.* 1991 CanLII 2721 (AB C.A.), (1991), 83 Alta. L.R. (2d) 289 (C.A.); *Fitz Randolph v. Fitz Randolph* (1918), 41 D.L.R. 739 (N.B.C.A.).

95 No circumstances are present which would bring this case within the above criteria and we are clearly not in as good a position as the trial judge to make the requisite findings. My colleague addresses this issue (at para. 33) only in relation to the finding of a duty to warn and justifies our addressing the issue on the basis that the "bulk of the critical evidence adduced at trial was documentary, not testimonial". This is not, however, the only factual issue which was not addressed at trial. We have two additional factual issues in respect of which there were no findings at trial:

(i)Would Ms. Hollis have consented to the operation even if properly warned?

(ii)Would Dr. Birch's conduct have been the same whether or not Dow was in breach of the duty to warn?

96 With respect to the first issue, notwithstanding that it was not dealt with by the trial judge, my colleague concludes (at para. 47) that "there was sufficient evidence adduced at trial to satisfy the subjective *Buchan* test". La Forest J. recognizes the concern expressed by Laskin C.J. that this test places too high a premium on the self-serving evidence of the plaintiff. In his view (at para. 46), however, this concern is adequately addressed "through cross-examination and through a proper weighing by the trial judge of the relevant testimony". I do not understand how the concern of Laskin C.J. is addressed when the evidence was not weighed by the trial judge and is dealt with on the basis of the subjective *Buchan* test for the first time in this Court. The hallmark of this test as explained in *Buchan* is acceptance of the evidence of the plaintiff on the assertion that she would

not have consented to the operation. Ms. Hollis was asked at trial what she would have done if advised of "all of those complications". She replied: "I would not have had the surgery". If, as explained by Robins J.A. in *Buchan*, the entire issue turns on whether the trial judge gives credit to this statement and the evidence of expert witnesses as to what other reasonable women would do is not relevant, then it is vital that the trial judge make a specific finding as to the credibility of this statement. The fact that in this case the trial judge made no adverse finding with respect to this statement and accepted her evidence on other issues cannot be a substitute for a finding on this crucial issue. Indeed, the trial judge made no comment with respect to Ms. Hollis' credibility or demeanour as a witness in general. A trial judge or jury is perfectly at liberty to accept part of a witness's evidence and reject other parts. We do not know whether he would have done so in this case.

97 On the other hand, if the testimony of experts was relevant, five plastic surgeons testified that many women were not deterred by possible complications. This evidence conflicted with the evidence of Ms. Hollis and could only be resolved at trial.

98 My colleague resolves the second causation issue (namely, whether or not Dr. Birch would have passed any warnings along), by effectively deciding that this aspect of causation does not arise. As explained above, my colleague's approach flies in the face of well established legal principles by eliminating the need for the plaintiff to show that her injuries would not have occurred had Dow warned the "learned intermediary". Clearly, the issue of causation must be resolved. In the absence of a finding in this Court that evidence was lacking to raise the issues or that a weighing of the evidence cannot resolve the matter, a new trial should be ordered for the purpose of enabling the trial judge to carry out this function.

99 Apart from the foregoing, there are three additional reasons for ordering a new trial in this case.

100 First, there will be a new trial in any event with respect to Dr. Birch, and the judgment of this Court will not put an end to the litigation.

101 Second, the issue as to whether Ms. Hollis would have proceeded with the implant if properly warned is an issue in the new trial ordered in respect of Dr. Birch. That order is not in issue here. Dr. Birch is entitled to raise the issue of causation. If this Court determines that issue and decides that on the evidence Ms. Hollis would have refused consent, I cannot see how a trial judge could decide otherwise. If he did, such inconsistent findings would not enhance the image of justice.

102 Finally, under the *Negligence Act*, where damage or loss is caused by the fault of two or more persons, liability for the damage must be apportioned in accordance with the degrees of fault. In accordance with s. 2 of the *Negligence Act*, the trial judge will have to determine the degree to which Dr. Birch was at fault. This involves a comparison of the degrees of fault of Dow and Dr. Birch. Such a comparison is at worst impossible and at best extremely difficult without hearing and weighing the evidence of negligence with respect to each defendant. It is, therefore, the practice to have a joint trial which includes as parties all those alleged to be at fault for having caused the damage or loss claimed. It is in keeping with the intent and purpose of the *Negligence Act* that all parties alleged to be at fault should be before the trial judge at the end of the case. See *McCarroll v. Powell*, [1955] 4 D.L.R. 631 (Ont. C.A.), at pp. 635-36; *Hunt v. MacLeod Construction Co.*, [1958] S.C.R. 737. The problem that I foresee for the trial judge is that the evidence with respect to Dow's breach of duty will have to be tendered but presumably in the absence of Dow as a party. The trial judge will not, however, be free to evaluate this evidence free of the opinion of this Court. For example, the trial judge might be of the view that on the evidence before him or her no fault is established. Yet he or she must find some fault because this Court has determined that Dow was at

fault. Moreover, unless Dow is able to re-inject itself into the proceedings, its degree of fault will be determined *ex parte*.

103 Accordingly, I would allow the appeal and direct a new trial as proposed by Southin J.A. dissenting on this issue.

Appeal dismissed with costs to the respondent Susan Hollis, SOPINKA *and* MCLACHLIN JJ. *dissenting.*

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